Title of Thesis Industrial Design in Endoscopy -

The Development of a Tissue and Organ Extractor

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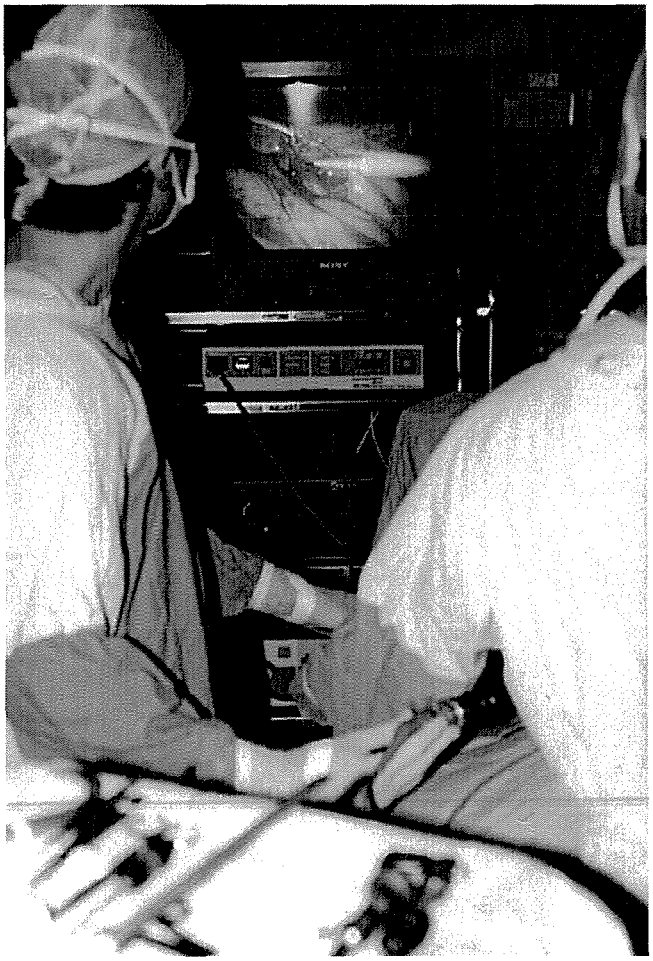
"Diseases that cause harm call for treatments that harm less." (William Osler 1849 - 1919).



Abstract

Throughout history, developments in medicine have aimed to improve patient quality of life, and reduce the trauma associated with surgical treatment. Surgical access to internal organs and bodily structures has been traditionally via large incisions. Endoscopic surgery presents a technique for surgical access via small (10mm) incisions by utilising a scope and camera for visualisation of the operative site. Endoscopy presents enormous benefits for patients in terms of lower post operative discomfort, and reduced recovery and hospitalisation time.

Since the first gall bladder extraction operation was performed in France in 1987, endoscopic surgery has been embraced by the international medical community. With the adoption of the new technique, new problems never previously encountered in open surgery, were revealed. One such problem is that the removal of large tissue specimens and organs is restricted by the small incision size. Instruments have been developed to address this problem however none of the devices provide a totally satisfactory solution. They have a number of critical weaknesses:

- The size of the access incision has to be enlarged, thereby compromising the entire endoscopic approach to surgery.
- The physical quality of the specimen extracted is very poor and is not suitable to conduct the necessary post operative pathological examinations.
- The safety of both the patient and the physician is jeopardised.

The problem of tissue and organ extraction at endoscopy is investigated and addressed. In addition to background information covering endoscopic surgery, this thesis describes the entire approach to the design problem, and the steps taken before arriving at the final solution.

This thesis contributes to the body of knowledge associated with the development of endoscopic surgical instruments. A new product capable of extracting large tissue specimens and organs in endoscopy is the final outcome of the research.

Acknowledgements

Few projects can be attributed to the sole work of one individual. As the designer and author of this thesis, I would like to sincerely thank the following people for their generous support and assistance throughout this project.

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Finally and most importantly I wish to thank my family, and close friends for their continual support, and patience over the last three years. In particular I wish to thank Rita Pereira, and Irené Ostash for their help and assistance in conducting many of the experiments.

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Statement of Authorship

The work contained in this thesis has not been previously submitted for a degree or diploma at any other higher educational institution. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made.

Signed: QUT Verified Signature Jonathan L'Estrange Tighe

Date: 30/5/97

CHAPTER 1

Introduction

"Learning without thought is labour lost; thought without learning is perilous."
(Confucius 551 - 479 BC)

Medicine is about getting better. Unfortunately many of the treatments employed to cure disease, cause more harm to patients than the disease itself. In response to this situation, less traumatic methods of treatment have been developed, and continue to be developed.

This thesis demonstrates the use of Industrial Design to develop surgical instruments, enabling less traumatic techniques of operative therapy to be adopted.

1.1 Minimal Access Surgery and Endoscopy

In recent years there has been a trend towards replacement of open surgery with less invasive procedures (Clover, 1992). Some treatments now totally avoid penetration of the body, e.g.- shock wave therapy in the treatment of kidney stones, and the use of stereo tactic radio surgery in the treatment of some artery and cerebral tumours (Hirsch, Hailey, 1992).

Open surgery uses a large incision to gain access to the internal organs of the body. Techniques have been developed which minimise the trauma associated with accessing the internal structures of the patient, while not compromising exposure of the operative field (Cuschieri, et.al., 1992b; Hirsch, Hailey, 1992). These techniques are commonly described as Minimal Access Surgical (MAS) techniques.

MAS techniques are generally achieved by using a small scope to gain access to the operative site, rather than the traditional large incision. This is known as endoscopic surgery, or surgery which occurs at the 'end of a scope'(also derived from the Greek *endo* meaning *within* or *internally*). Endoscopic surgery is the general term for scopically conducted operations, laparoscopic surgery refers to surgery of the lap (abdomen), thoracoscopic surgery refers to surgery of the chest, and arthroscopic refers to surgery of the joints (Hirsch, Hailey, 1992; Hulka, 1985). However this project is only concerned with laparoscopy and thorascopy. Figure 1 shows a laparoscopic operation in progress.

The general procedure involves the following steps:

1. A large needle is introduced into the patient, through which gas is injected to expand (insufflate) the abdominal cavity (Figure 1a).
2. Other incisions are then made to accommodate a scope, forceps, suction/irrigation equipment , and other surgical devices (Figure 1b).
3. The required treatment is performed (Figure 1c).
4. At the end of the procedure the instruments are withdrawn and the gas expelled.

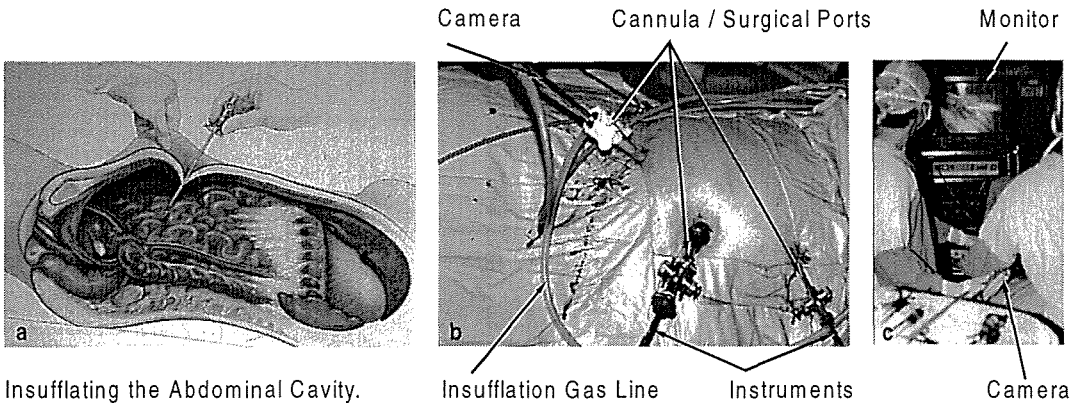


Figure 1 Laparoscopic General Procedure.

(a).Insufflation (Semm, et.al., 1989). (b).The Abdomen During Endoscopy, and (c) A View Over the Surgeons Shoulder.

Insufflating the abdominal cavity with gas creates a space for the physician to work in. Insufflation is not commonly used in thoracic procedures as the chest wall is naturally self supported by the ribs (Kaiser, Daniel, 1993). Instead, the lung on the operative side is deliberately collapsed to provide a space for surgical manipulation (Matar, 1994).

For the patient, endoscopy has the following benefits over traditional open surgery. These benefits have been supported and elaborated in research by these experts: (Bruhat et.al., 1992; Cuschieri, Berci, 1990; Conway, 1993; Cuschieri, et.al., 1992b; Delaitre, 1992; Glinatsis, et.al., 1992; Green, Ponsky, 1994; Grundfest, 1993a; Hirsch, 1993; Hirsch, Hailey, 1992; Hulka, 1985; Jones, 1993a; Kaiser, Daniel, 1993; Miller, 1992; McArena, et.al., 1992; Schirmer, 1993; Silbertrust, 1993; Tulman, et.al., 1993; White, 1993; Zucker, 1991).

- There is a lesser amount of anaesthesia required. Some operations are performed under local anaesthetic, and many are performed on an outpatient basis.
- The trauma caused by surgical access is significantly reduced.
- The instruments used for endoscopy are physically smaller. The smaller instruments do not require organs to be displaced nearly as much as when using a human hand. The smaller instruments work on a finer scale and thus cause less therapeutic damage.
- Blood loss is reduced, as incision and cut sizes are reduced.
- Exposure of internal organs to open air induces a drying effect which can cause problems, endoscopy avoids this.
- The smaller incisions result in reduced cosmetic damage.

- The reduced wound size decreases the chance for infection or contamination during surgery, and post-operatively.
- The overall effect of the reduced trauma results in an earlier discharge from hospital and a faster return to normal lifestyle.

In circumstances when the frailty of a patient has prevented surgery from being a viable treatment option, the reduced trauma of endoscopy can offer a solution (Cuschieri, et.al., 1992b). Figure 2, illustrates the fundamental advantage of endoscopic procedures over open techniques - reduced trauma associated with surgical access. Image 2(a) shows a traditional approach to gall bladder surgery (large traumatic incision). Image 2(b) shows the same operation being performed endoscopically (several small incisions).

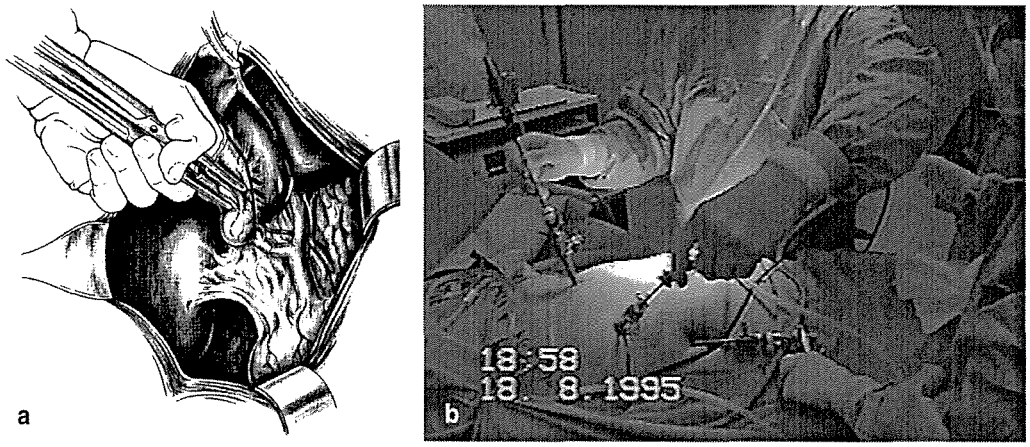


Figure 2 Gall Bladder Operation.

(a).Traditional Open Approach. (b). Endoscopically Conducted Procedure (Schwartz et.al. 1993).

Due to the significant improvements in patient quality of life that endoscopic surgery offers, the technique has been rapidly adopted world wide since its introduction to general surgery in 1987 (Clayman, 1994; Cuschieri, et.al., 1992b).

1.2 Endoscopic Tissue and Organ Extraction

With the adoption of endoscopy, new problems never previously encountered with open surgery, were uncovered (Hirsch, Hailey, 1992; Cuschieri, Berci, 1990). With open surgery a physician looks directly upon the operative site, and grasps tissue directly by hand. Hand held sterile sponges and swabs are used to wipe away blood and fluid. Large excised tissue pieces or organs can be grasped and pulled through an incision without incident.

The closed nature of endoscopy has demanded that many of the basic principal techniques taken for granted and used in everyday surgery, be rethought and redeveloped (Cuschieri, Berci, 1990). Cameras, scopes, and 300mm thin, long instruments are used to visualise and manipulate tissue (Figure 1b, 1c, p17). Suction and irrigation implements wash away blood and suck up fluid from the operative site. The removal of large tissue specimens and organs is restricted by the incision size (Cuschieri, et.al., 1992a).

This thesis is specifically aimed at addressing the problem of removing organs and large tissue specimens in endoscopy. Surgeons have the tools and skills to mobilise many organs from their surrounding tissue and connective structures (Hirsch, Hailey, 1992; Cuschieri, et.al., 1992a). The source of the problem is that the incision size is typically only 10 - 12mm. The most common technique of organ extraction for endoscopy, is to encapsulate the organ in a plastic bag and then draw the bag and contained organ out an enlarged incision. This process of enlarging an incision is a complete compromise of the endoscopic approach, and forfeits many of the benefits associated with Minimal Access Surgery (Kanehira, et.al., 1994). This technique is at present being used for extraction of a variety of specimens, e.g.: kidneys, spleens, appendixes, gall bladders, tumours.

Devices to solve this problem do exist, however none of them provide a total and acceptable solution to the problem. The designs are too expensive, or too difficult and complex to use, or unsafe, or simply not effective (Chapter 3, p96).

Thesis Aim

To research the field of endoscopic surgery, and design an internationally marketable product for the extraction of large tissue specimens and organs in endoscopic surgery.

Thesis Objectives

Present the community with a potentially, genuinely beneficial product, that further enables surgeons to perform good medicine, and competent designers to provide innovative solutions.

Provide a contribution to the body of knowledge available to those investigating toward developing a medical instrument.

Construct a working prototype of the device. Provide more than a theoretical solution by physically proving the design is capable of performing the intended task.

Market the intellectual property arising from the project to the appropriate companies.

1.3 Significance of Endoscopy and the Need for a Tissue Extraction System

In 1987 one of the most significant events of modern surgery occurred. Dr P. Mouret and his assistants performed the first laparoscopic cholecystectomy (gall bladder removal) in Lyons, France (Dowling, 1992). Since that day, the world has witnessed the most significant development of modern surgery in terms of patient care, and the biggest market explosion in medical history (Hirsch, 1993).

Significance for Patients and the Community

Patients want to get better. Endoscopic surgery helps them attain this faster, safer, and more comfortably. The length of hospitalisation is dependent on both the conditions of the disease and the nature of the treatment. By performing an operation endoscopically rather than using the traditional open approach, a patient's hospital stay can be reduced by 3-4 days. In addition, their return to normal lifestyle can be reduced by several weeks, to a period of approximately 7-14 days (Conway, 1993; Cuschieri, 1992; Gaur, et.al., 1993).

When applied to thoracic surgery these figures become even more significant. There is major trauma caused by cutting between and spreading ribs. Hospitalisation of 10-14 days is common, and a full recovery takes many months. Thoracoscopy avoids the large traumatic incision and thus reduces the hospital stay to days, and the recovery period to only 2-3 weeks (Landreneau et.al., 1992).

The improved return to normal lifestyle has real benefits to both the community and the patient in terms of reduced cost. When a person takes leave and has an operation there are two costs, direct and indirect. Direct costs include e.g. theatre fees, hospital charges, and instrument expenses. Indirect costs are much more difficult to quantitatively assess because they include expenses from e.g. time off work, stress to individuals and families, increases in medical insurance, and decreases in available hospital beds (Grundfest, 1993b; Weatherly, Young, 1994). Endoscopy does not appear to significantly reduce direct costs, but indirect costs are substantially lessened.

The lack of a suitable instrument for endoscopic organ extraction is preventing patients and the community from enjoying the full benefits of Minimal Access Surgery (Hirsch, Hailey, 1992).

Market Size

A well designed instrument has the potential to be used for any clinically suitable endoscopic organ or large tissue specimen extraction operation conducted. This encompasses: gall bladder removal, appendectomy, spleen or kidney extraction, and any other operation where the surgeon wishes to remove a large morsel out a small incision. In the United States, over 500 000 people had their gall bladder removed in 1993. (Cagir et.al., 1994, Grundfest, 1993b, Hirsch, 1993; Miller, et.al., 1991). Supposing that an appropriate extraction device was used for 10% of these operations, then a product turnover of 50 000 units per annum would result. Although a detailed market analysis was not within the scope of the research conducted, the above outlined initial figures, combined with early response from industry, lead to the conclusion that there is a market for an endoscopic tissue and extraction device (BISHOP, 1994).

Significance for Designers

This thesis provides a body of knowledge to designers. The literature contained in this thesis is relevant to anyone working in the field of industrial design. There is information specifically beneficial to those designing or developing sterile surgical devices, and endoscopic medical implements. Important and practical observations regarding the user as a surgeon/nurse are documented for future reference. The entire thesis will serve as a useful case study to anyone conducting a research and/or a product development project within the industrial design or medical profession.

Industrial design has been criticised as being a profession aimed at creating products "people don't need, to buy with money they don't have, to impress others who don't care" (Papanek, 1985). The involvement of industrial design in the medical industry presents an opportunity for the benefits of design to be used for a humane and morally beneficial purpose. Good design has been described as a moral issue, where the designer is motivated by emotions of sympathy to cater for others needs (Heath, 1993). The design of a device for the extraction of tissue and organs in endoscopy presents real benefits to the

community and the patient, and additionally the project has the potential to be commercially viable.

1.4 Design Research Methodology Outline

Prior to formally commencing this project, general research was conducted into the field of laparoscopic surgery. The problem of removing large tissue specimens was uncovered, and the research area was altered to encompass thorasoscopy, and targeted toward the problems of organ extraction.

Investigations examined both the user requirements of surgical instruments, and the necessary functional aspects of the relevant apparatus. In several sections throughout the thesis reference is made to 'user approach'. A 'user approach' represents the method by which a user achieves a task. By varying the characteristics and product interface features of a device, the 'user approach' toward a problem can be controlled or guided to optimise usability and user benefit. In short, a 'user approach' represents the proposed method for the user (in this case a surgeon) to interact with, and operate a proposed device.

Chapter 5 (Design Development and Methodology) is comprised of the following four sections, relating directly to the four main stages of the design methodology:

Stage 1 - Research
Stage 2 - Invention
Stage 3 - Definition
Stage 4 - Solution.

Research. With the commencement of the thesis, detailed investigation of the problem began. A user profile, and a list of criteria pertaining to user needs was compiled. The necessary functional goals of the design were established.

A 'user approach' was conceived and development began.

An analysis of existing organ extraction devices was conducted, and the compilation of an extensive design criteria list started. The design criteria checklist established during this "research" phase was continually updated and added to over the entire course of the project.

Invention, the first stage of development, aimed to achieve a functional mechanism or device, which had the potential to satisfy all of the required design objectives. As functional characteristics of the product were investigated, so were developments of the user approach.

Definition, the second stage of the project defined the functional operation and the user approach of the product. The device had been shown to fulfil all of the essential functional requirements. The proposed user approach was presented to surgeons and approved.

Solution, the third stage of development involved addressing all of the remaining design criteria, and forming a marketable design solution. Many sessions of user testing and analysis were conducted. The design concepts were evaluated, and a final design was proposed, thereby representing the design freeze. An initial design for a product package was also presented.

The overall research and design methodology is discussed in detail in Chapter 5. Along with the discussion, a graphical representation of the methodology is presented.

1.5 Overview of Thesis

Chapter 1 provides an introduction to the thesis. A background to Minimal Access Surgery and Endoscopy is provided. The specific area of research is presented in relation to the wider topics of endoscopic surgery and industrial design. The significance of the research is discussed. An overview of the entire thesis is outlined. Chosen terminology are defined. Limitations and key assumptions of the research are presented.

Chapter 2 presents a literature review. A brief history of endoscopic surgery is given. Details pertaining to patients are outlined. Relevant information on anaesthesia is discussed. The instruments and equipment used in endoscopy and the surgical theatre are shown. The basic surgical techniques used by physicians are presented. Relevant laparoscopic and thoracoscopic procedures are detailed. Design issues in endoscopy are discussed.

Chapter 3 provides an analysis of organ extraction in endoscopy. The available techniques for extracting an organ are assessed. The various instruments currently available which, aim to extract large tissue specimens or organs at endoscopy are analysed. A study of a number of currently available encapsulation bags is conducted.

Chapter 4 lists the design criteria established over the course of the project. Categories include:

- Aim
- Functional Requirements
- Surgeon / User Needs
- Nurse / User Needs
- Marketing Requirements
- Production Requirements
- Packaging Criteria
- Case Specific Criteria.

Chapter 5 presents the design research methodology used. The chapter structures the four stages of the project chronologically:

- Research: Establish a User Approach
- Invention: Achieve Function

- Definition: Specify User Method and Product Function
- Solution: Formation of a Marketable Product

Chapter 6 presents the final design solution. The design concept is outlined. The intended method for operating the device is shown. The design details are specified. Each physical and operation feature of the design is justified in this chapter using the results of Chapter 5 as a basis.

Chapter 7 provides a closing to the thesis. Fulfilment of thesis aims and objectives are discussed. Conclusions are drawn about the wider subject of endoscopic surgery, and the current status of tissue extraction in endoscopy. Comments about the design research methodology used for this project are presented. There are conclusions drawn about the final design proposed (endoTES). Recommendations for Industry, which have arisen from the thesis are outlined. Finally, areas in need of further research are presented.

1.6 Definition of Chosen Terminology

Two terms have been used to describe this new approach to surgery: Minimally Invasive Therapy (MIT), and Minimal Access Surgery (MAS) (Hirsch, Hailey, 1992). Minimal Invasive Therapy has been suggested as inappropriate, because surgery is always invasive, and there is a poor correlation between invasiveness and risk (Cuschieri, 1990). Minimal Access Surgery is adopted because the most significant aspect of scopic surgery, is the reduction of trauma associated with accessing the internal structures of the body (Cuschieri, 1990).

In several places throughout this thesis reference is made to length of time for an operation. The period of time that an operation takes is measured by the skin to skin time. 'Time on' commences when the first incision is made, and 'time off' is taken at the completion of closing of the last incision.

1.7 Limitations and Key Assumptions

Details given about medical conditions, and operations are only there to provide an overview of the essential information relevant for this project. An important distinction to bear in mind when reading this thesis is that it has been written by an industrial designer and not a doctor, and therefore the focus of the thesis is focused toward user analysis and the design process, not medicine and surgical therapy.

Details of the instruments and equipment outlined are only an available sample of the products.

The list of procedures for which the final design may be useful, is generalised, as opposed to a detailed critique of situations when it may be inappropriate to use the device. Should the final design be commercially developed and clinically tested, then extensive feedback would be given by the medical community, leading to further improvement of the design. New applications for the use of the design would be uncovered, and appropriate and inappropriate situations for using the product defined.

The design of a product package is highly dependant on the available and accepted packaging techniques of the manufacturer. As no specific manufacturer has been defined for the final design, the package design has only been resolved to a conceptual level.

An extensive study into the cost of using the proposed design was not within the scope of the project, and not possible with the available time and resources. If the project was commercially adopted than such a study would be recommended and most certainly conducted.

1.8 Summary

This chapter has provided a foundation on which to base the rest of the thesis. An introduction to minimal access surgery and endoscopy has been provided. The problem of large tissue specimen and organ removal in endoscopy is presented. The aim and objectives of the thesis are given. The significance of conducting a study into the field of tissue and organ extraction for endoscopy is demonstrated. The design research methodology used to conduct the thesis is outlined. A brief summary of each chapter is given. Chosen terminology are defined, and limitations and key assumptions of the thesis are shown.

CHAPTER 2

Literature Review

"Knowledge is of two kinds, we know a subject ourselves, or we know where we can find information upon it." (Samuel Johnson 1709 - 1784)

By exploring the surroundings in which an implement is used, a better understanding of the needs of the user is attained. Many of the requirements which a product must meet are highlighted by investigation of the contextual environment in which the product exists (Popovic, 1993).

There is the need to examine the following distinct issues before the design of a new implement can begin. The history and development of endoscopy, the physical and emotional status of the patient, the anaesthesia and level of consciousness of the patient, the instruments and medical equipment used in an endoscopic operation, the basic surgical techniques and manoeuvres employed by the surgeon, the details of the procedures for which the new instrument will be used, and also the design issues unique to endoscopy need to be recognised.

The knowledge presented in the following chapter (Chapter 2), establishes a base to conduct the analysis into tissue extraction in endoscopy (Chapter 3). The research established in Chapter 2, combined with the results of the analysis outlined in Chapter 3, is used to initiate the design criteria checklist described in Chapter 4.

2.1 A Brief History of Endoscopy

Modern endoscopy had its origins in the early 19th century when physicians first began inspecting the "open-cavities" using scopic devices (Hulka, 1985; Kaiser, Daniel, 1993). Light was provided by kerosene lamps, candles, and later hot platinum wire. The devices were crude painful, and difficult to gain any useful observations from. It was not until Edison invented the light bulb in 1880 and the Germans improved optical systems in the 1890's that the endoscope became a practical instrument (Figure 3),(Chad, Davis, 1992).

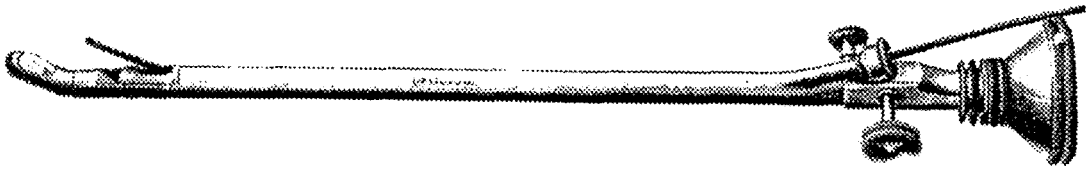


Figure 3 19th Century Cystoscopes

Incorporating: Urethral Cannula, Light Source, and Mirror (Marlow, 1976).

2.1.1 The Development of a Technique for Laparoscopy

1901 - Jacobaeus, Sweden. The Swedish physician conducted a diagnostic inspection of the peritoneal cavity of a human without insufflating the cavity with gas (Cuschieri, et.al., 1992b; Hulka, 1985; Green, and Ponsky, 1994).

1902 - Kelling, Germany. Kelling used a cystoscope to inspect the peritoneal cavity of a dog after first creating a pneumoperitoneum with filtered air (Cuschieri, Buess, and Perissat, 1992; Hulka, 1985; Zucker, 1991).

1929 - Kalk, Germany. To provide a better field of view for diagnosis of liver and biliary tract disorders, Kalk pioneered an oblique lens system which provided 135 degree view (Green, and Ponsky, 1994). In addition Kalk was the first physician to advocate a dual puncture technique, allowing increased procedure complexity and allowing the development of operative laparoscopy (Cuschieri, Buess, and Perissat 1992; Hulka, 1985).

1933 - Fevers. From his own experience with 50 patients, Fevers recommended changing the insufflation gas from room air to O_2 or CO_2 (Cuschieri, Buess, and Perissat, 1992).

1934 - Ruddock, America. By modifying a pair of biopsy forceps, Ruddock was able to use monopolar electrocautery during laparoscopy (Cuschieri, Buess, and Perissat, 1992; Hulka, 1985).

1936 - Bosch, Germany. Tubal sterilisation was performed with high frequency monopolar electrocoagulation of the fallopian tubes using a low frequency generator (100W) (Cuschieri, Buess, and Perissat, 1992).

1938 - Veress, Hungary. Veress developed a needle for the creation of a safe pneumothorax (deliberate collapse of the lung). The device consisted of a sharp needle that would automatically retract back over a rounded stylet upon entering a cavity (Hulka, 1985). (Current Veress needles in Figure 21, p63).

1941 - Barnes and Power, America. The American physicians used a high output generator (350W) for tubal sterilisation, however due to poor equipment insulation and improper use, extensive morbidity and deaths resulted from burns to adjacent tissues (Hulka, 1985). The technique was abandoned for mechanical methods of achieving tubal ligation.

1944 - Palmer, France. Although the quantity of gas being used to achieve adequate insufflation was being carefully monitored, no attention was being given to the intraabdominal pressure. Palmer first stressed the importance of monitoring intraabdominal pressure and inspired the development of such a device (Hulka, 1985; Zucker, 1991).

1952 - Hopkins, Britain. Prior to 1952, endoscopes were constructed using a series of lenses along a predominantly hollow tube. Hopkins interchanged the air and lenses, creating a solid scope with a much higher refractive index. Hopkins invention was one of the most crucial inventions in operative laparoscopy as his device dramatically improved image quality and brightness (Cuschieri, Buess, and Perissat, 1992; Zucker, 1991).

1960's - Hot tungsten light sources were replaced with cold fibre optics (Davis, 1992).

1960's - Semm, Germany. The Kiel school headed by Professor Kurt Semm developed many instruments from which modern endoscopy is derived (Cuschieri, et.al., 1992b). Some of the instruments to come from the school include: header probe, variable flow with automatic feed back insufflators, lavage equipment and surgical trainers. Semm was also responsible for

pioneering basic laparoscopic surgical skills including: dissection, ligation (external and internal) and suturing (Davis, 1992; Zucker, 1991).

1986 - The development of the chip camera enabled the image from the scope to be displayed onto a video display screen. This enabled surgeons and their assistants to work in unison and under more control (Zucker, 1991).

1987 - Less than one year after the introduction of the chip camera, the first laparoscopically guided gallstone clearance was performed (Zucker, 1991). From the development of this procedure, and its rapid international acceptance the largest market explosion in modern medical history followed (Hirsch ,1993).

Following the advert of laparoscopic cholecystectomy, other forms of endoscopic surgery have developed. The various procedures now being performed via the new approach are shown in Appendix 1, p255.

2.1.2 The Development of Thoracoscopic Surgery.

1925 Jacobaeus Sweden - Thorascopy was first described and practised on humans by Jacobaeus in Stockholm when in 1925 he induced a pneumothorax to collapse a lung, then cauterised and divided adhesions between visceral and parential pleura in a patient suffering tubulosis (Kaiser, Daniel, 1993; Zucker, 1991).

1948 Goetze - The first denervation procedure was developed and performed by Goetze. He performed a non-selective sympathectomy (Cuschieri, Buess, and Perissat, 1992).

1950 Wittmoser - Over a period of three decades Wittmoser developed many of the procedures and instrumentation that modern thorascopy stems from, including: selective thoracic vagotomy of the bronchial and abdominal branches, selective sympathectomy of the rami communicates, and retroperitoneal sympathectomy (Cuschieri, et.al., 1992b).

1989 Cuschieri, Nathansen, Scotland - The scope of thoracoscopic surgery was enhanced by the development of the multi puncture technique. The extra ports allow the performance of such procedures as: ligation of bullae and pleurectomy for recurrent spontaneous pneumothorax, oesophagus mobilisation and diffuse oesophageal spasm (Cuschieri, et.al., 1992).

2.2 The Patient

Media attention has stimulated high patient demand for endoscopic operations over traditional open procedures (Zucker, 1991). Unfortunately it is not always possible to use a closed technique. Patients are chosen selectively for their suitability to a scopically conducted operation. Informing the patient prior to surgery about their treatment, and providing post-operative care are as important to an individuals health as the therapy itself.

2.2.1 Patient Selection

Not all patients are suitable candidates for laparoscopy procedures. Numerous conditions present favourable and unfavourable conditions for the technique (Hulka, 1985).

Absolute Contraindications

The absolute contraindications are: patients suffering severe cardiac disease, uncontrollable bleeding disorders, unstable abdominal injuries caused by gunshots and high velocity missiles, irreducible external hernia, a pelvic mass rising above the umbilicus, and or chronic respiratory failure (Bruhat et.al., 1992; Hulka, 1985).

High Risk Patients

Patients regarded as high risk have such contraindications as: previous abdominal surgery inducive to substantial adhesion formation, abdominal distension by ascites or gas forcing the intestinal loops upward toward trocar entry points, bleeding and coagulation disorders, obesity, and cardiorespiratory disease (Hulka 1985; Kaiser, and Daniel, 1993).

Low Risk Patients

A patient is considered as low risk if they have none of the above mentioned conditions, and: have no systemic disease, be anaesthetic Class I status, have had no previous abdominal surgery, have no history of Pelvic Inflammatory disease, not to be obese, be multi parous having delivered

awake and vaginally, and be comfortable and relaxed during bimanual pelvic examination (Hulka, 1985).

2.2.2 Informing the Patient

Prior to any operation patients are informed of all the details the procedure entails. Included in this explanation is possible expected complications, particularly if there is a chance of conversion to open laparonomy. Post operative anger (and possible lawsuit) are avoided by being completely honest and up front with the patient. If a patient falls in the high risk category then they are made totally aware of their situation and the resulting possible outcomes.

With elective surgery, e.g. sterilisation, it is particularly important for the patient to understand their situation. Patients must be totally happy, confident and contented with their decision to have surgery. This is achieved by extensive counselling with the physician and nurse and an explanation of all options and consequences.

2.2.3 Postoperative Care

Appendices 4, p261, and 5, p262, contain an example of typical preoperative and postoperative instructions given to patients undergoing laparoscopic procedures. The instructions address the most common concerns of patients. Patients remain too disorientated and drowsy from anaesthetic and medication to remember verbal instructions, so all details are written down (Hulka, 1985). A return visit to the hospital or doctors clinic is scheduled one week after the operation. If however the patient feels that all is well then he/she is instructed to cancel the appointment.

2.3 Anaesthesia

Conventional open procedures require long hospital stays and severe post operative pain. Endoscopic procedure have dramatically reduced both the length of stay and level of post operative pain (Zucker, 1991). In some instances, procedures are performed on an outpatient basis.

Anaesthetic techniques have been developed to cope with the short hospital stays and rapid return to normal lifestyle. Thus the goals of the anaesthetist are: Hemodynamic and respiratory stability, appropriate muscle relaxation and control of diaphragmatic excursion (Kaiser, and Daniel, 1993).

2.3.1 Particular Concerns of the Endoscopic Anaesthetist

Regardless of the type of anaesthesia, the anaesthetist aims to keep the patient relaxed at all times. If the patient is not relaxed and the intraabdominal pressure becomes excessive then a bucking period may be induced. If muscles contract with pain, then grasped organs can be ripped and torn, or touched with a coagulation tip. During surgery the surgeons attention is focused on the scope, thus the anaesthetist aids in the monitoring of intraabdominal pressure. Under local anaesthesia pressures between 12-15 mmHg are comfortable, higher pressures are avoided as ventilation difficulty can occur and acute anxiety can begin (Nathansen, 1996).

Carbon Dioxide Embolism

Carbon dioxide is used to create pneumoperitoneum because it has a relatively innocuous effect on the peritoneal surface and is highly soluble in the blood stream.

The CO_2 absorbed from insufflation produces an increased P_aCO_2 level. This change in P_aCO_2 level alone is not enough to cause a gas embolism, however if there is one or a combination of : excessive intraabdominal pressure, excessive bleeding, open venous channels, and or steep reverse Trendelenberg position, there is a greater chance that a gas embolism may occur (Hulka, 1985).

When a gas embolism forms in venous circulation it causes a gas lock in the right ventricle or atrium, this obstructs venous return to the right heart chambers producing a huge drop in cardiac output, eventually leading to cardiac arrest and death. The anaesthetist constantly monitors the heart for signs of a gas embolism. The condition is treated by immediate cardiopulmonary resuscitation and the insertion of a central venous catheter for gas aspiration.

2.3.2 Selection of the Anaesthetic Technique

The general considerations in choosing an anaesthetic technique for endoscopy are very similar to those for traditional open procedures. The two main additional considerations are that: approximately 5% to 10% of all laparoscopic procedures are converted to open laparonomy operations, and that anaesthesia should be short acting to aid patient return to normal lifestyle (Hulka, 1985).

General Anaesthesia

General anaesthesia was originally the only technique used and still remains the most utilised. Patients are usually young and in good health. An anaesthetist's caution increases if the patient has a history of - chronic heart failure, intra cranial hypertension, spontaneous pneumothorax or pulmonary emphysema (Kaiser, and Daniel, 1993).

The main advantages of general anaesthesia are:

-Cadiopulmonary status and $PaCO_2$ levels are better controlled.

-Endotracheal intubation protects airways.

-Total muscle relaxation minimises patient motion (Hulka, 1985).

Regional Anaesthesia

Thoracic epidural anaesthesia in combination with nerve segment blocking is used for laparoscopic procedures. Careful patient selection and a co-operative surgical team is required for this technique.

The advantages of regional anaesthesia are that :

-The patient is awake.
-Airways are intact and have natural reflexes.

Deep sedation is avoided so that controlled ventilation can be guaranteed.

Local Anaesthesia

Local anaesthesia is only suitable for short procedures of a diagnostic nature. The technique is not adequate for complex surgery despite patient co-operation and motivation. Many clinicians do not use local anaesthesia because of the high patient discomfort, despite the advantages of early hospital release (Clover, 1992; Hulka, 1985).

Vocal Local. An essential part of local anaesthesia is the presence of a "vocal local" (Hulka, 1985). The "vocal local" is a sitter who talks to the patient and continually reassures that all is going well and explains the sensations they are experiencing. This vital position can be assumed by the surgeon. It is important to make the patient the centre of attention in the operating theatre.

2.3.3 Anaesthesia for Thoracoscopy

To perform laparoscopic surgery, the physician creates a pneumoperitoneum to provide space for manoeuvring in. In thoracoscopy, to create a 'working space' the surgeon induces 'one lung ventilation' by deflating the lung on the operative side (Kaiser, and Daniel, 1993). By ventilating the non-operative side and collapsing the lung on the operative side, visualisation of the intrathoracic structures is achieved.

To achieve one lung ventilation the anaesthetist introduces an endotracheal tube. Incorporated into the tube are an upper and lower inflatable blocking balloons. The blocking balloons seal off the lungs such that the only air which can enter / exit the lungs must do so via the endotracheal tube. The anaesthetist directly controls the amount of air circulating through the endotracheal tube, thereby regulating the amount of air reaching the lungs (Kaiser, and Daniel, 1993). This apparatus is illustrated in Figure 4.

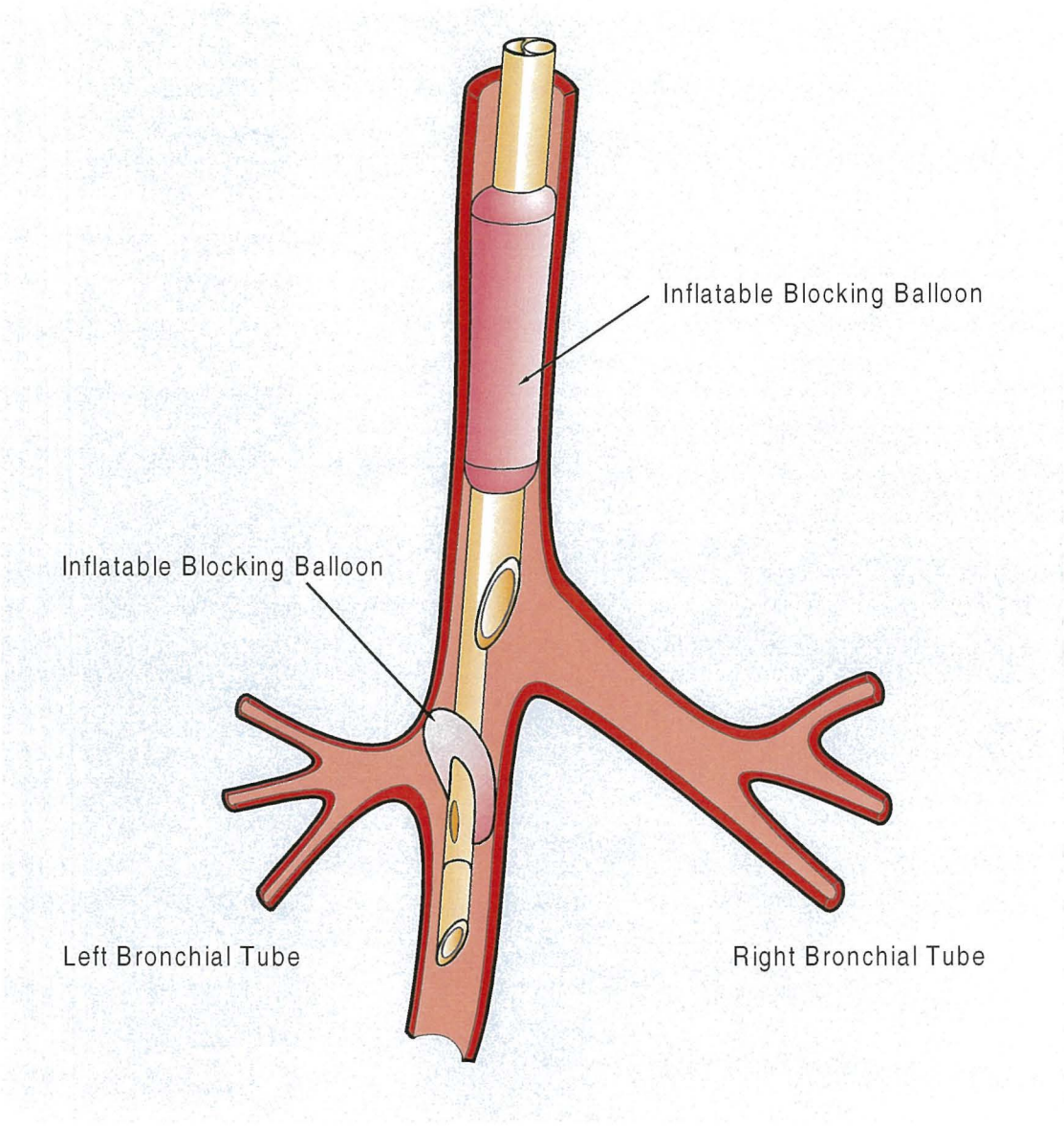


Figure 4 Endotracheal Tube

Device Utilised to Achieve One Lung Ventilation.

2.4 Endoscopic Instruments and Equipment

The instruments and equipment used in minimal access surgery are distinctly different from those used in open procedures (Bruhat et.al., 1992). The nature of endoscopy imposes a number of constraints on implements, e.g.: limited access, remote handling, pressurised environment. These constraints are directly responsible for the physical characteristic of the equipment.

2.4.1 Room Layout

Operating theatres are designed to be a flexible working environment. All equipment is mounted on movable trolleys except the operating table and lights. Figure 5, shows a typical room layout, and the medical staff which work in the theatre. The details of this set-up change depending upon the specific operation being performed.

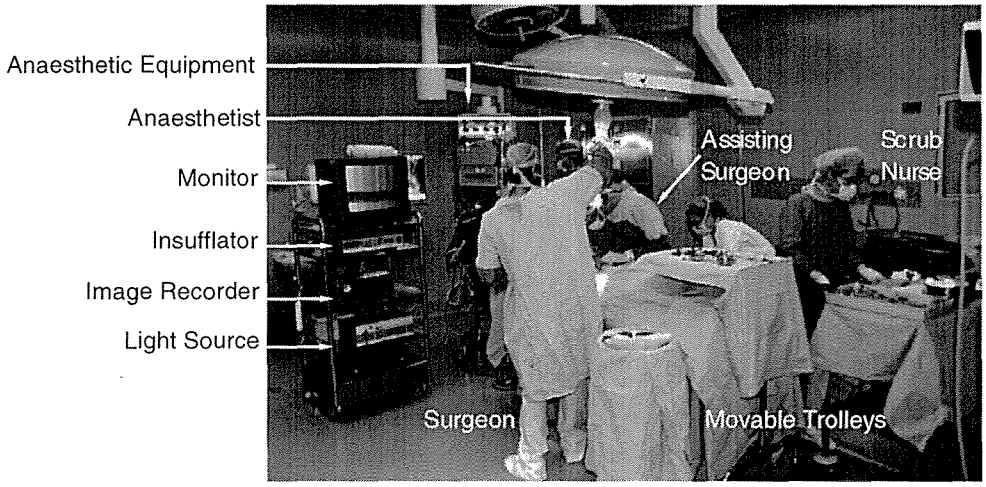


Figure 5 Typical Operating Room Layout.

The placement of the monitor/s for endoscopy is important and sometimes difficult. The monitor is the link between surgeon and patient, and also provides the assisting staff with a view of the operation. Without a view of the operation the assisting surgeon and scrub nurse cannot effectively assist the surgeon (Zucker, 1991). Difficulty can arise when trying to position the monitor so that everyone has an adequate view. Many theatres now use two ceiling mounted monitors to improve the situation.

Operating theatres are designated clean rooms. All personal entering the room have to wear the appropriate theatre attire. This usually includes pyjama like outfits, a head covering, and a surgical mask. Within the room there is the sterile field, in which the surgeon, camera operator, and sterile nurse work. All three wear a sterile gown, gloves, and frequently a face shield. Supporting the sterile team are several scout nurses which are responsible for introducing instruments and non sterile equipment into the operative theatre.

The large quantity of equipment produces a huge number of electrical cords and irrigation tubing. Although the bulk of the cords are situated at the rear of various pieces of equipment there is still a large volume of connectors entering the sterile surgical environment. To keep the situation under control, all connectors leave and enter the sterile field at one point. At this point there is a clamp or fixing mechanism to prevent slipping.

2.4.2 Visualisation Equipment

In traditional open surgical procedures, the physician looked directly onto the operative site. In scopically conducted procedures, the surgeon relies on a remote image displayed on a television monitor. To provide the high quality image, high resolution scopes, cameras, and monitors are used.

Scopes

The endoscope provides visualisation of the thoracic or peritoneal cavity. It consists of a series of lenses housed in a stiff rod. The lenses are surrounded by a bundle of fiberoptic cables which provide light inside the cavity.

Endoscopes are available in diameters ranging from 1.9mm to 14mm, with a variety of viewing angles (Figure 6). Straight 0° scopes are the easiest to control and orient, however their ability to obtain an overall view by looking down onto the operative site is limited. For this reason many surgeons chose to work with 30°-40° angled scope.

Some operations only require one access port to conduct the procedure. To facilitate this, scopes have been developed with an integral instrument channel.

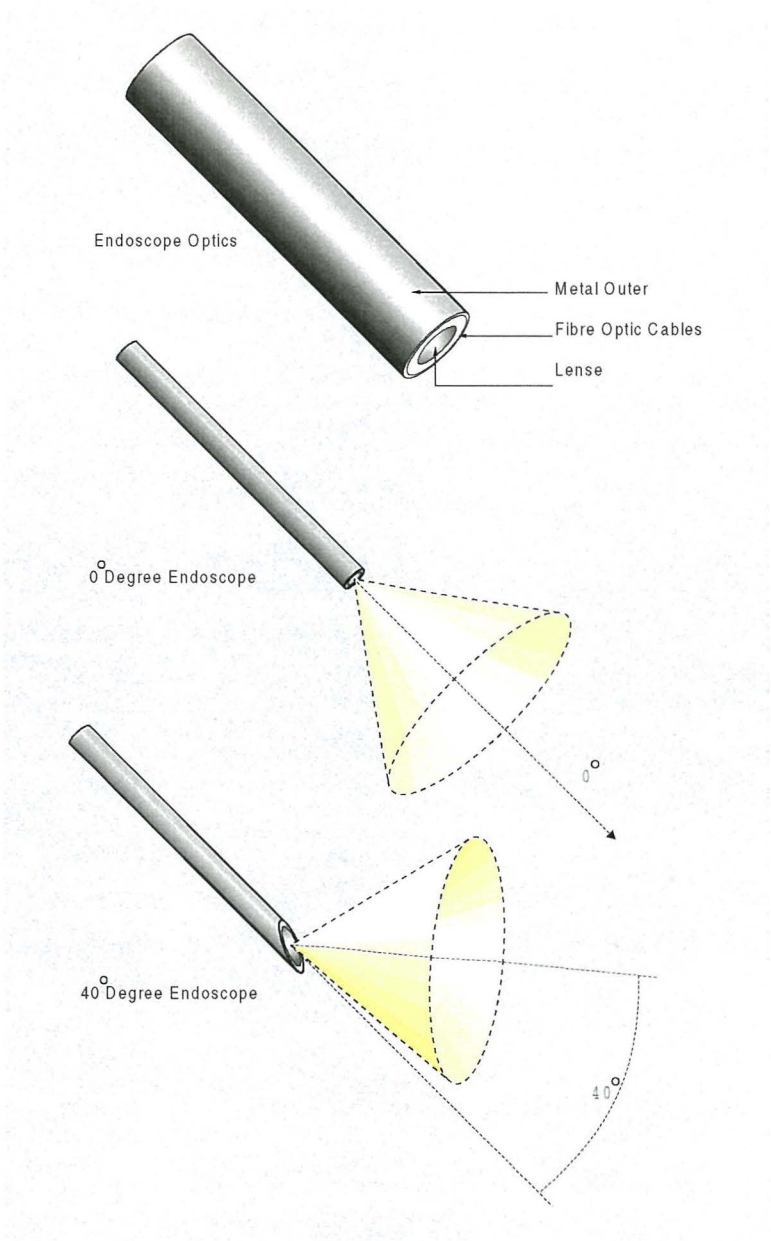


Figure 6 Endoscopes, and the Various Viewing Angles.

One of the main difficulties the surgeon has to overcome when performing a scopically conducted operation is the loss of depth perception (Cuschieri, and Berci, 1990). In an attempt to solve the problem stereoscopic endoscopes are under development. The instruments are expensive and still require refinement. With continued development and research stereoscopic systems will provide a major improvement in the user interface between surgeon and patient.

Light Sources

Light is generated in a remote unit, heat filtered, and then transmitted along fiberoptic cables to the scope. The heat filter removes heat from the delivered light, producing 'cold light'. Even though a substantial amount of the heat has been removed from the light, the high intensity still produces elevated temperatures at the end of the scope. If held in one position for an extended period of time the scope is capable of drying or even burning tissue. The quality of the light inside the cavity is important as it directly affects the perceived colour and texture of tissues.

Video Imaging

Visualisation of the operative field is achieved using an end viewing chip camera. The camera is attached to an image processor which interprets and displays the image onto a video screen. High resolution images are essential to safely and satisfactorily perform surgery.

Accurate colour and contrast are required, thus the cameras have built in 'white' and 'colour' balancing features. Automatic focusing keeps the image on screen clear and crisp. Magnification features are utilised to vary the image between a close up view for fine work, 1:1 for a 'realistic' view, and wide view for surveying the entire field.

Cameras, scopes, and cables are all sealed so that they can be soaked for sterilisation. Unfortunately this process does shorten their working life (Gomella, et.al., 1992). Plastic sterile sleeves are sometimes used to cover the equipment , removing the need for soaking.

High resolution, large screen monitors are used for image display. The monitor is placed in the direct line of sight of the surgeon. In many theatres a second monitor is utilised to display the image to the assisting staff.

Image recording

A variety of systems are available for image recording. Most commonly used is a video recorder. Laser disks are available but their cost is prohibitive. For capturing still images, digital still video image capture systems are available. The images are stored on small disks from which hard copy print outs can be made. The printouts are inserted into patient files, or used for illustration to other colleagues.

2.4.3 Insufflation Equipment

All surgical techniques require space for manoeuvrability. To achieve this in laparoscopy, the peritoneal cavity is enlarged by filling it with gas. Insufflation is achieved by injecting gas through an insufflation needle or trocar into the peritoneal cavity. A good pneumoperitoneum provides room for surgical techniques and adequate view of the operative area (Hulka, 1985). Insufflation devices have been designed to safely create and maintain pneumoperitoneum at the appropriate pressure (Bruhat et.al., 1992; Cuschieri, and Berci, 1990).

Choice of Gas

Throughout history, insufflation has been achieved with many different gases including; room air, nitrous oxide, oxygen, and carbon dioxide (Hulka, 1985). Air and oxygen create a higher risk of gas embolism, and support combustion, making them totally unsuitable for use with electrocautery or laser devices. Nitrous oxide was discarded because of uncontrollable and unpredictable absorption into the blood stream, not to mention possible erratic behaviour of the operative staff. Carbon Dioxide remains the choice for insufflation as it suppresses combustion, when absorbed into the blood stream has no serious effect on metabolism, is readily available, is inexpensive and easy to use (Cuschieri, and Berci, 1990).

Insufflators

Insufflators (Figure 7) regulated the flow of carbon dioxide into the abdominal cavity. The surgeon is able to pre-set the desired intra-abdominal pressure and gas flow rate into the cavity. An insufflator will also display the current intra-abdominal pressure and the total volume of gas injected. High gas flow rates of 30 l/min are required to maintain pneumoperitoneum during periods of extensive suction.

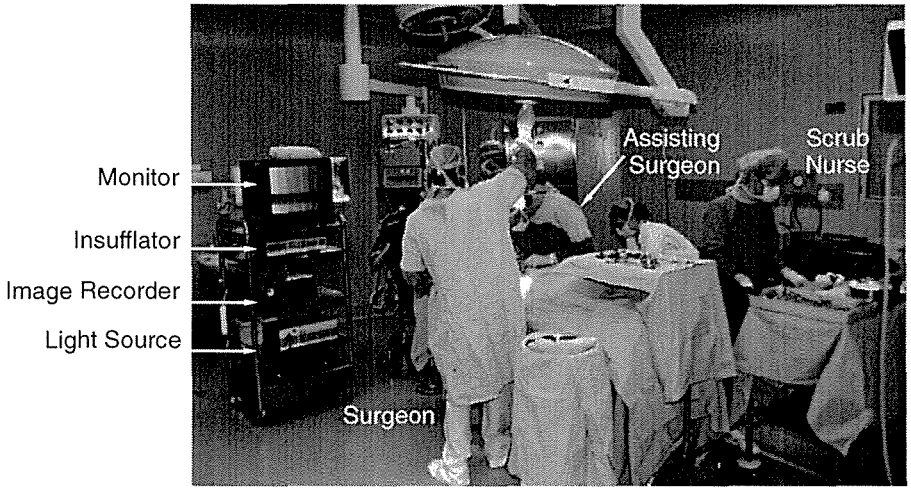


Figure 7 Endoscopic Equipment and Operating Room.

2.4.4 Hand Instruments

Endoscopic hand instruments are adaptations from those used in open surgery. The most easily recognisable feature of almost all endoscopic tools is the long shaft, which connects the surgeons hand and operative site. As endoscopy has developed, the instruments have become more complex and more specific task oriented. The basic instrumentation used in all endoscopic operations includes: insufflation needles, trocar /cannula, suction / irrigation devices, forceps, cutting implements, clips / staplers, and sutures. Almost all instruments are available in a disposable or reusable design. Where possible, an example of each design is provided, along with a brief comparison between the single-use and multi-use products.

Insufflation Needles

Insufflation needles (Figure 8) are used in laparoscopy to create pneumoperitoneum prior to introduction of the first trocar. Needle designs are all based upon the Verses needle. The needle is inserted into the peritoneal cavity. Upon entry a blunt shield protrudes past the sharp tip preventing inadvertent injury to under lying structures. Disposable and reusable designs are available, the advantages of the disposable needle being guaranteed sterility and sharpness.

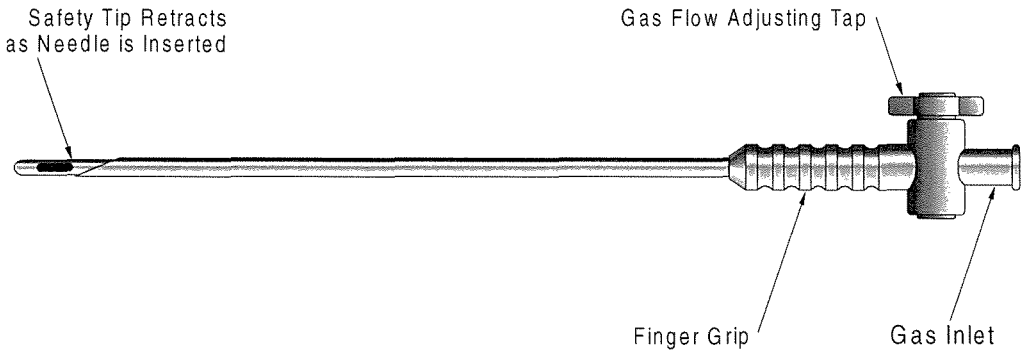


Figure 8 An Insufflation Needle.

Trocar and Cannula

Where open procedures use a large incision to gain access to the internal structures, endoscopy uses one or multiple entry ports passing through small incisions. Instruments are constantly being inserted and removed from the ports throughout the procedure.

To create these ports, a cannula containing a sharp trocar is inserted. Once the cannula is through to the peritoneal or thoracic cavity the trocar is removed, permitting the introduction of other instruments. Inadvertent injury of internal viscera remains one of the main concerns in all endoscopic procedures. To address this, trocars have a safety shield that covers the sharp tip upon penetration of the facia. Manufacturer's, US Surgical and Johnson & Johnson have released a trocar that allows optically controlled penetration.

For laparoscopy, pneumoperitoneum has to be maintained, thus all cannula have built in seals and valves to prevent the escape of CO_2. In thoracoscopy there is no pneumoperitoneum, therefore the cannula do not require valves and seals.

There are advantages and disadvantages associated with disposable and reusable surgical ports (Figure 9). Physicians weigh up the cost and associated benefit when selecting which instruments to use for a procedure. The main influencing factors are shown in Figure 10a p48, Figure 10b p49.

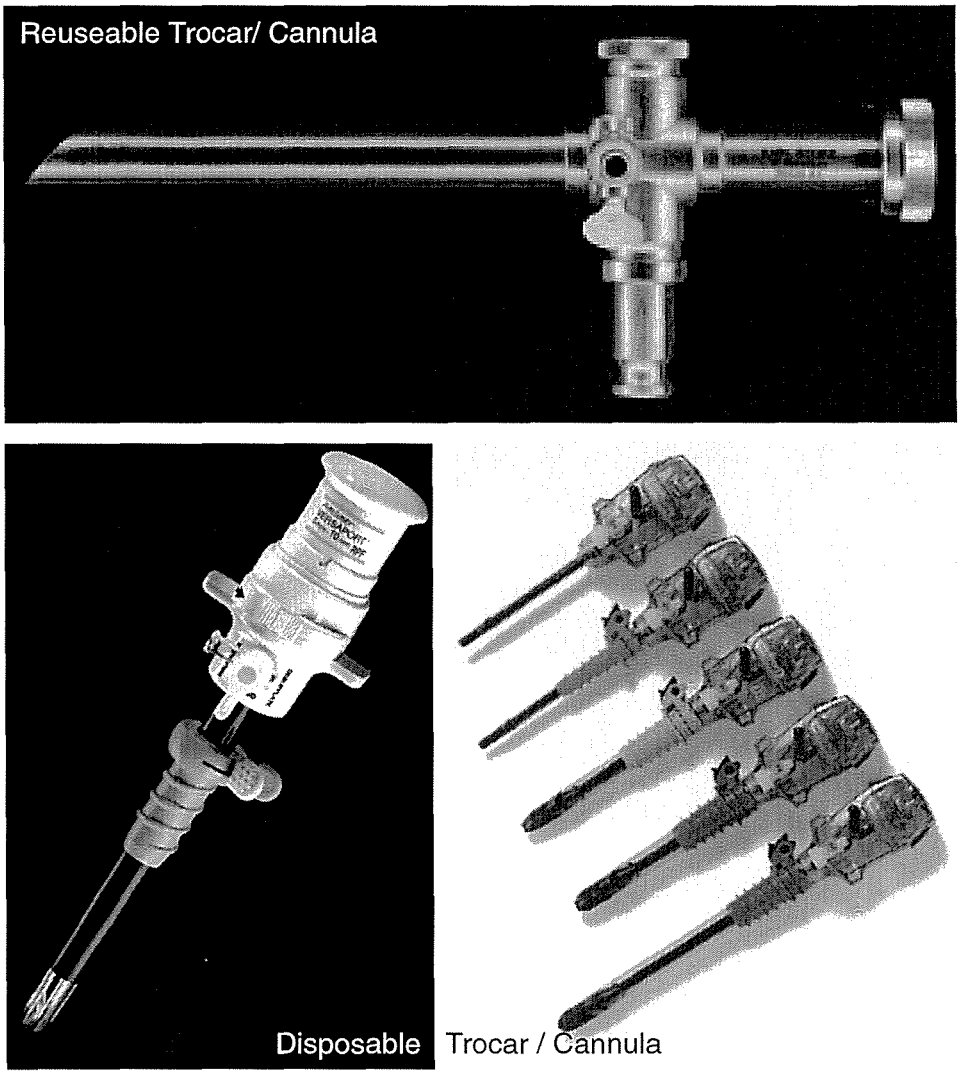


Figure 9 Disposable and Reusable Surgical Ports.

(AutoSuture, 1995; Johnson & Johnson, 1994,).

Advantage of reusable device:	Advantages of disposable devices:
- Cost contained to once off purchase price, and maintenance required. - Reduced environmental cost.	- The trocar is always sharp. - The sharp tip automatically retracts upon entry. - Fibreglass sheaths are radio translucent. - The spring loaded flap valve automatically opens and closes as instruments are inserted and removed. - Gripping threads prevent inadvertent removal of the cannula.

Figure 10a Advantages of: Reusable / Disposable Cannula Trocar.

Disadvantage of a reusable device:	Disadvantage of disposable device:
- The trocar can become blunt, thus greater force is required to penetrate into the cavity, possibly resulting in dangerously uncontrolled entry. - The trocar does not automatically retract upon entry. - The spring loaded trumpet valve has to be pushed to remove or insert an instrument. - They need to be dismantled after each use for sterilisation. - They are radio opaque and thus interfere with mid operation x-rays and cholangiograms.	- Continual cost of re-purchasing. - Environmental cost of increased consumption of resources.

Figure 10b Disadvantages of: Reusable / Disposable Cannula Trocar.

Many physicians choose to use a disposable cannula for the first puncture, then use reusable devices, under direct visual control, for any additional punctures.

Suction / Irrigation Equipment

Operative procedures by nature produces bleeding and loose material which covers and inhibits the visual field. In traditional open surgery this material can be easily removed by swabs, sponges or suction. The closed nature of endoscopy prevents the use of swabs or sponges to clear the visual field, thus placing greater reliance on suction capabilities (Bruhat et.al., 1992). High flow suction and irrigation machines have been developed which are capable of rapidly spraying an area with fluid, and then sucking up the water and loose material (Figure 11).

Suction / irrigation devices, also known as lavage implements, are used in the hydro-dissection of tissue planes. The water stream produced from the irrigation handle will not affect a vascular tissue structure, but it will separate two thin film like tissue planes.

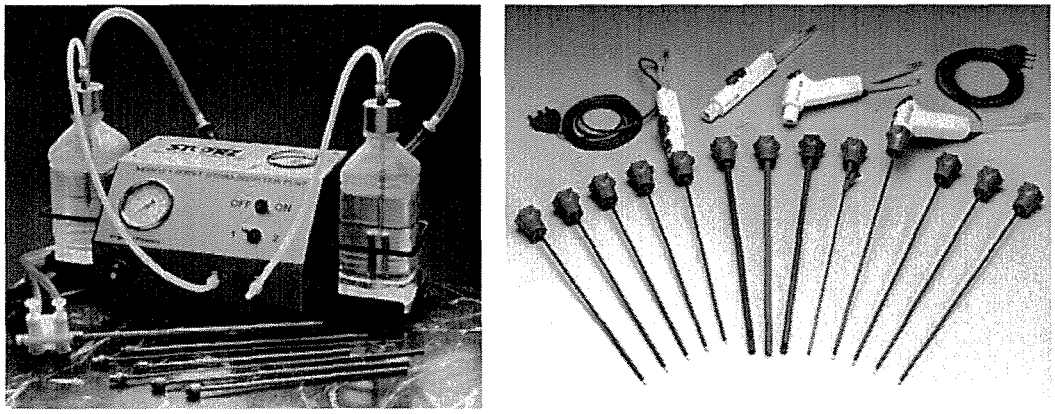


Figure 11 Lavage handle and Suction / Irrigation Machine.

(Semm et.al., 1989; Johnson & Johnson, 1994)

The advantage of disposable lavage handles over reusable handles is guaranteed sterility and no cleaning is required.

Forceps

Forceps are used for grasping, dissection, and with the appropriate connections, electrocoagulation (Figure 12). A very wide variety of designs are available, all with different shapes, spring mechanisms, locks and hinges. Aside from their purchase costs, disposable devices have the advantage of guaranteed sterility, and reliable operation. Due to the small hinges and long shafts, reusable devices are difficult to clean and sterilise, and the intricate workings are subject to malfunctioning.

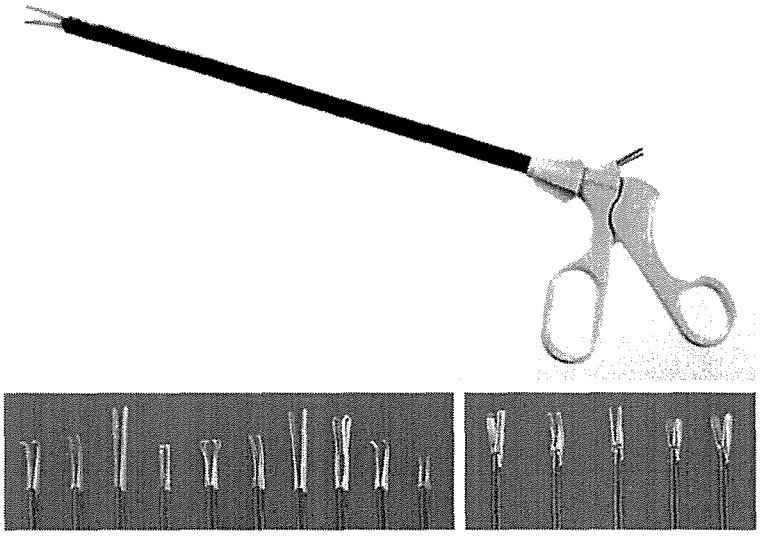


Figure 12 Grasping Forceps.

(Johnson and Johnson, 1993)

The severity of the jaw teeth will affect the amount of tissue trauma. Very course teeth can be used on non-fragile organs while fine toothed (atraumatic) jaws cause almost no tissue damage, however the grip strength is reduced. When performing tissue dissection, forceps are connected to diathermy equipment so that any blood vessels encountered can be immediately cauterised.

Scissors

There are three basic types of scissors: hook, straight, and curved (Figure 13). Hook scissors allow tissue to be gripped prior to cutting. This allows the surgeon to grasp a structure, and pull it away from surrounding tissues prior to cutting. Straight scissors are useful for continuous tissue cutting. Curved scissors allow accurate visualisation of the structures being dissected.

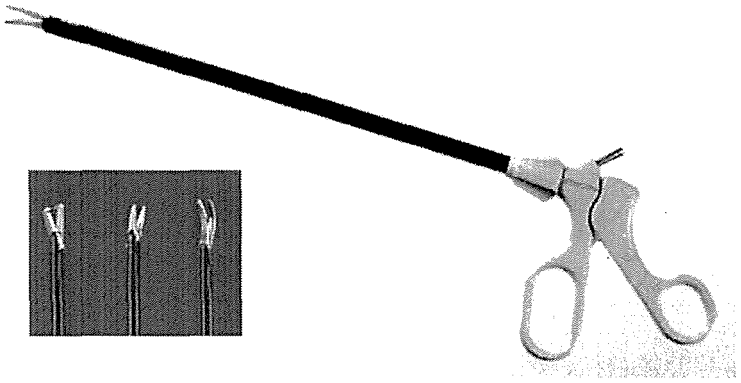


Figure 13 Endoscopic Scissors.

(Johnson & Johnson, 1993).

Notice the common grip handle used by Johnson and Johnson for their range of forceps and scissors (Figure 12, p50, and 13).

Disposable scissors have the following advantages:

- Disposable scissors are always sharp. Scissors quickly become blunt , particularly when used for diathermy.
- The mechanics of scissors are small and precise and difficult to clean.
- They are available with controllable flexible tips.

Staplers and Clip Appliers

Clips and staples are used extensively in endoscopic surgery (Figure 14). Clips provide a quick and simple method of occluding and fastening structures. Clip applicators fasten a small titanium or bioabsorbable plastic U-clip around a structure.

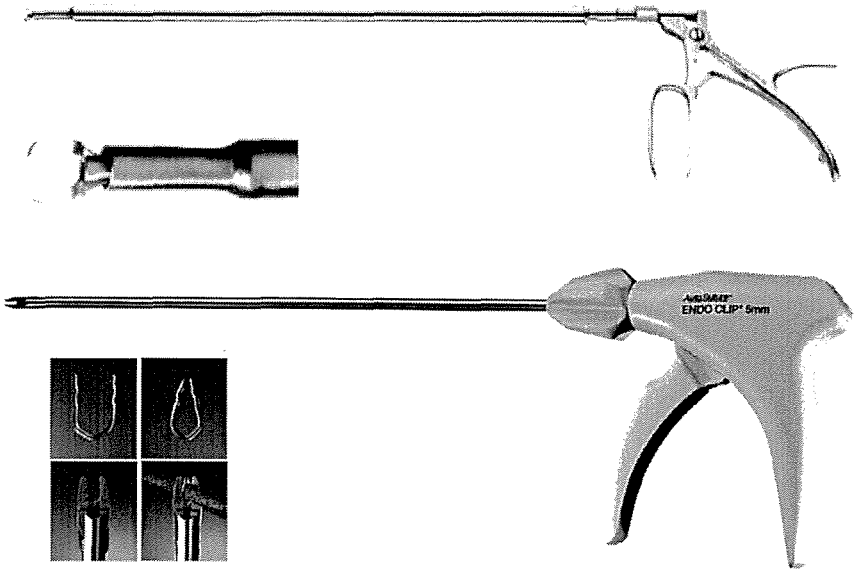


Figure 14 Reusable and Disposable Clip Applier.

(Semm, 1989; AutoSuture 1994)

In deciding which clip applier to utilise, the following advantages and disadvantages associated with disposable and reusable devices are considered Figures 15a, 15b).

Advantage of disposable device:	**Advantage of reusable device:**
- Sterility guaranteed - Automatic reloading of staples without removal from the patient, up to twenty reloads. - Shorter operating time.	- Once off purchase cost. - No wastage of unused clips.

Figure 15a Advantages of: Reusable / Disposable Staplers.

Disadvantage of disposable stapler:	Disadvantages of the reusable stapler:
- Continual cost of repurchase.	- Reloading requires the stapler to be removed from the abdomen after each staple application. - Difficult to sterilise staples. - Clips can be knocked out of the device as it is entered down the canal. - Longer operating time.

Figure 15b Disadvantages of: Reusable / Disposable Staplers.

When deciding whether to use a disposable or reusable device, a physician will base their decision on how many clips have to be applied during a procedure. It is uncommon for a disposable stapler to be used when less than 10 clips are being applied in a procedure.

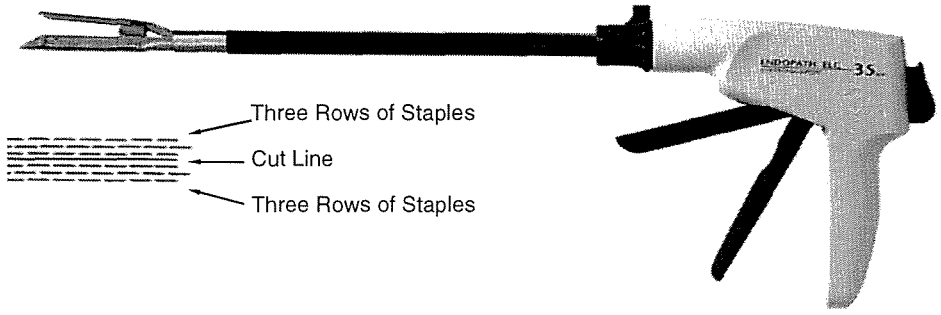


Figure 16 Endo-GIA Stapler.

(Johnson & Johnson, Advertisement, 1993)

Staplers are used extensively for tissue division. The stapler clamps around a structure, then fires two triple rows of staples, and then divides the tissue within the jaws (Figure 16). Such devices are widely used to dissect across several vascular structure in one step. Similar devices have been developed for the asmoisois of the colon following anterior resection.

2.4.5 Thermal Instruments

In open surgery, sponges and swabs are commonly used to achieve haemostasis. The closed environment of endoscopy prevents the use of

sponges, thus making haemostasis a problem (Bruhat et.al., 1992; Cuschieri, Buess, and Perissat, 1992). A variety of heat instruments and methods, including thermocoagulation, electrocautery, and laser devices have been developed to achieve clean dissection and haemostasis of blood vessels (Cuschieri, and Berci, 1990).

Thermocoagulation

Thermocoagulation is the process of raising the temperature of an object which through thermal conductivity heats up the tissue in contact. The applied heat causes the tissue to dry out and induces haemostasis. For example; applying a heated metallic probe to tissue will cause coagulation. By controlling the temperature (100°C) of the heated element, haemostasis can be achieved without carbon formation, or the probe becoming stuck to the coagulated tissue (Cuschieri, Buess, and Perissat, 1992).

Hot gas probes and plasma scalpels work on a similar principle. An inert gas such as argon or helium is heated up to 3000°C in an electric arc. The gas is focused to a fine cutting jet less than 1mm in diameter. Gas thermocoagulation provides haemostasis without contacting tissue. The quantity of heated gas being expelled is very small and loses excessive thermal energy within millimetres of the outlet.

Electrocautery

Also known as diathermy, electrocautery is the application of high frequency electrical current to tissue to achieve haemostasis or dissection. The electrical current can be managed by two methods, monopolar electrocoagulation, and bipolar coagulation.

Monopolar coagulation involves attaching a neutral electrode to the leg of the patient (Figure 17). By pressing a pedal the surgeon applies current through a fine tip or forceps. The concentration of electrical current at the point of contact between the instrument and tissue produces coagulation. By varying tip shape and current level, the physician can coagulate or dissect tissue.

To ensure safe use of monopolar coagulation, recommended product operational instructions are strictly adhered to (Bruhat et.al., 1992). A slipped neutral electrode provides poor electrical conduction and causes extensive burning (Cuschieri, and Berci, 1990). The surgeon continually monitors that no remote site will be unintentionally coagulated (Hulka, 1985; Zucker, 1991).

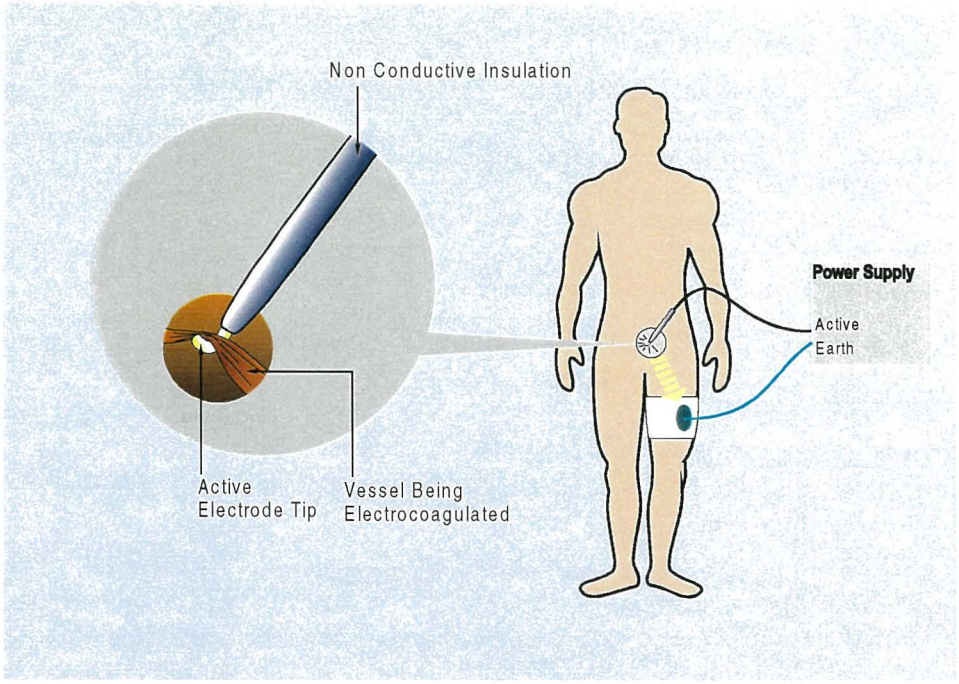


Figure 17 Monopolar Coagulation.

Bipolar coagulation is much safer than monopolar surgery as both electrodes are situated at the instrument tip (Bruhat et.al., 1992; Cuschieri, and Berci, 1990; Hulka, 1985). Current flows from one electrode, into the tissue being grasped, then returns via the second electrode to the generator (Figure 18). The selected tissue is coagulated.

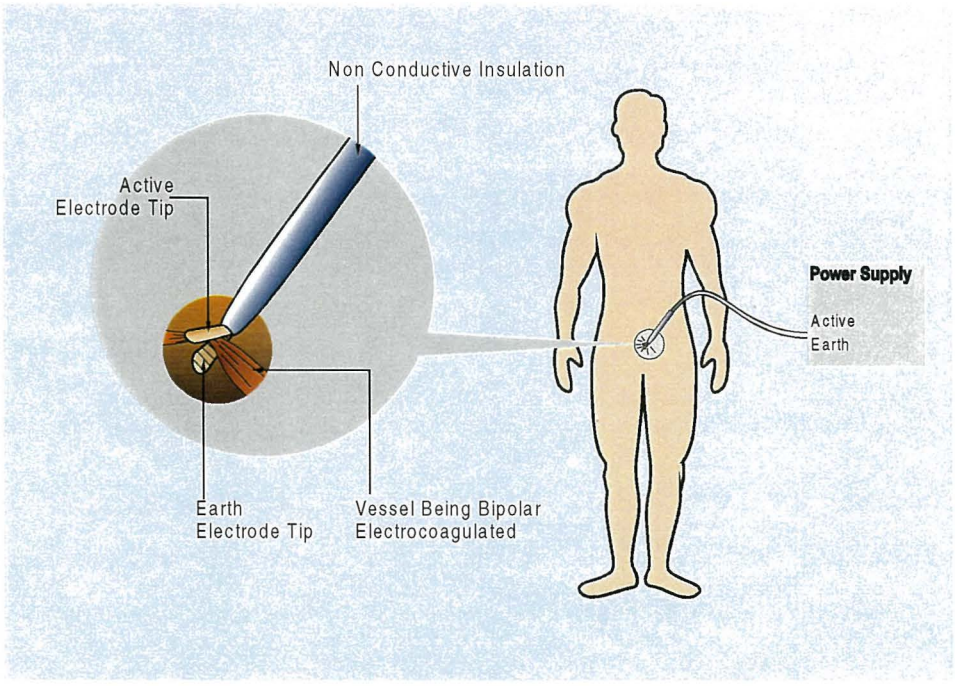


Figure 18 Bipolar Coagulation.

Laser

Lasers use photons of energy to dissect and coagulate tissue. The main advantage of the laser over electrocautery equipment is that the tissue damage is much more controlled and focused (Cuschieri, and Berci, 1990). There are two general types of laser used in surgery - free beam and contact tip laser.

Free beam lasers require accurate manipulation of the fibre tip to control the focal point. It is critical for the surgeon to be aware of the beams path at all times, as it can cause extensive damage to structures in the background. Contact tip lasers deliver the photons through a fiberoptic or sapphire tip. There is no focal point as the tip has to be in contact with the tissue for the laser to have any affect on tissue. Depending on the focal point in free beams, and the shape of fibre optic / sapphire tips, penetration depth of lasers varies from 0.1mm to 4mm.

Lasers are regarded as very effective and safe instruments for achieving coagulation and tissue dissection, however they are expensive to purchase, operate and maintain. Due to the lower expense, electro and thermal coagulation implements remain the more widely utilised instruments.

2.5 Basic Surgical Skills

There are a number of basic techniques used by surgeons to achieve specific goals throughout an operation. These manoeuvres are used many times during the course of a procedure. The technique of tissue and organ extraction could be considered a basic surgical skill used in a number of different operations. e.g. appendectomy, splenectomy.

This section describes three basic, but important surgical skills:

- Dissection, (separating connected tissue).
- Haemostasis, (inducing blood to coagulate and stop bleeding).
- Knotting and Suturing, (tying knots and sutures)

2.5.1 Dissection

Dissection is the process of separating connected tissues. This includes peeling apart tissue planes, cutting through vascular structures, and dissecting sections of an organ. The basic techniques and instruments available for performing dissection include: blunt dissection, scissors, electrosurgical hook knife, hydrojet, laser, and sharp scalpel.

The surgeon performs three steps when dissecting a structure.

1. Exposure of the specimen for dissection.
2. Stabilisation of the structure.
3. Dissection of the tissue.

Exposure

Exposure is achieved with the use of a retractor. Large structures such as livers require the use of fan shaped retractors and round ended rods for safe tissue manipulation (Figure 19). The large surface area of these retractors prevents handling injuries. Exposure of smaller structures is safely achieved with atraumatic forceps (Figure 12, p50).

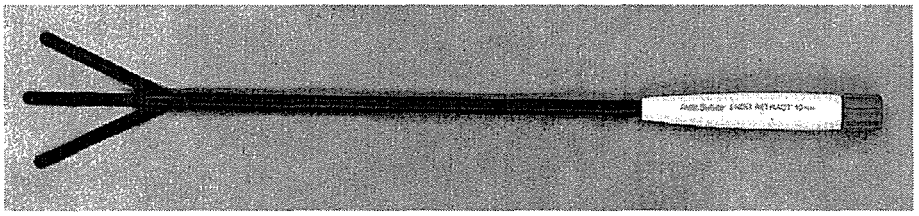


Figure 19 Endo Retractor.

Stabilisation

Once the relevant anatomy has been exposed, the retracting instruments are stabilised. In most situations this simply involves the surgeon steadying themselves, while the dissection implement is manoeuvred into place. In some rare situations several forceps are utilised to hold back adjacent tissue from the operative site. These forceps are then stabilised by fixation to the surgical drape or instrument clamps that attach to the side of the table.

Dissection

The chosen dissection implement is manoeuvred into place and the tissue is cut or separated.

Blunt dissection uses a pledget swab griped by traumatic forceps. The swab is pushed between tissue planes, separating the layers and absorbing fluid as it travels.

Scissors are always kept closed until they are situated at the cutting site. Scissors are used to cut through structures, or for tissue plane separation by opening the blades in a surface defect. When cutting through a structure, it is first electrocoagulated to prevent bleeding after dissection.

The electrosurgical hook knife is used in conjunction with monopolar electrocautery. The hook is used to catch the selected tissue then current is applied, dissecting the specimen. The heel of the hook focuses current on a small point and is commonly used for cutting through tissue. (Figure 20)

Hydrojet dissection is performed using the lavage device. Fluid is targeted between tissue planes to peel the structures apart. The big advantage of using fluid is that the operative site remains clean, and visible. Any oozing produced can be evacuated using the same device on suction. The application of a pressurised water stream will break down fat globules making the techniques especially useful for exposing vascular structures.

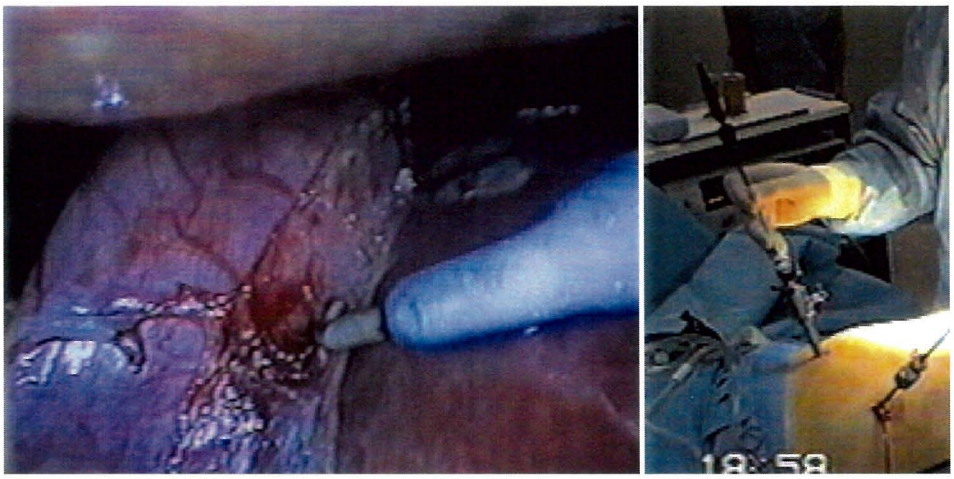


Figure 20 Electrosurgical Hook Knife in Operation.

Laser dissection is achieved by directing the implement at the desired tissue and applying the laser beam. Attention is always given to prevent burning through the chosen target and damaging an underlying structure.

Sharp scalpels are seldom used in endoscopy. There are the obvious risks associated with manoeuvring an exposed blade inside a body cavity. Introducing and removing scalpels from surgical ports can dislodge a blade, causing it to fall loose inside the patient.

2.5.2 Haemostasis

Haemostasis is the coagulation of blood to stop bleeding. One of the most significant limitations of endoscopy is the inability of a surgeon to swab a bleeding area (Cuschieri, and Berci, 1990). In open surgery, minor bleeding can be halted with the simple application of pressure. As this is not possible in endoscopy, other methods of achieving haemostasis have been developed. The application of thermal energy, electrical energy, clips, and sutures are used to stop minor bleeding.

Electrocoagulation

Electrical energy provides the most commonly used resource for achieving haemostasis in endoscopy. Current can be applied to tissue using either: scissors, forceps, or probe. Whichever instrument is already inserted in the patient is most often used. The surgeon performs four steps to achieve haemostasis:

1. The coagulation site is selected.

2. The appropriate instrument is manoeuvred into position, ensuring that no unselected areas will be inadvertently coagulated.
3. The current is switched on using a foot pedal.
4. The equipment will automatically switch off when optimal coagulation has been achieved.

Thermocoagulation

Thermocoagulation is performed in a similar method to electrocoagulation. The desired coagulation site is selected, the instrument is manoeuvred into place and the heat is activated. The heater tips of the instrument have been designed to heat up extremely quickly, and cool down equally quickly (Cuschieri, and Berci, 1990).

Clipping

Clips are available in either bioabsorbable plastic or metal designs. To apply a clip the surgeon grips the desired vessel with forceps and pulls it away from surrounding tissue. The clip is manoeuvred around the vessel and closed. The clip must be positioned at right angles to the vessel for reliable occlusion (Cuschieri, and Berci, 1990).

2.5.3 Knotting and Suturing

Vessel occlusion is achieved in endoscopy by the use of clips, staples, or knots. Clips and staples are commonly used in preference to knots and sutures because they are quick and simple to apply. However clips and staples are not always appropriate for the situation. Vessels with limited access prevent staplers from being used, and large diameter vessels cannot be secured with clips, so knotting and suturing techniques have to be used. Knotting material such as catgut or silk are designed to swell upon application. The swelling increases the knot strength and helps prevent slipping.

Knots can be divided into two distinct groups, internal and external. External knots are tied external to the patient and slid down a cannula into the patient. Internal knots are formed and tightened inside the patient.

Suturing is used to fix two tissue structures together. Typically a 26mm curved needle suture and two forceps are utilised. The suture needle is grasped and

inserted down the appropriate port. Care is taken not to knock the suture needle from the jaws of the forceps during insertion. A fixing knot is formed, providing the first suture. A suture is formed by passing a suture needle from the active forceps through tissue to the receptive forceps. The process is repeated to continue suturing. After each run the assistant picks up the slack and keeps a consistent tension on the suture (Cuschieri, et.al., 1992b).

2.6 Laparoscopic Procedures

The technique of laparoscopy is used to facilitate treatment of a large number of different aliments. Appendix 1, p255, contains a list of most of the operations performed using an endoscopic technique. The procedures outlined in this section are those particularly relevant to organ extraction. In addition to the operative procedures, details are given on the steps taken to incise the patient at the beginning of surgery, and the methods of wound closure used at the completion of treatment. Emphasis has been placed on the physical task of specimen extraction, rather than on the exact steps which the surgeon follows.

2.6.1 Initial Manoeuvres and Wound Closure

All laparoscopic procedures begin and end with a sequence of steps in preparation and conclusion, of the actual surgical treatment.

Patient Position

Prior to commencing laparoscopy, the patient is positioned for surgery. For all operations described below except hysterectomy, the patient lays flat, shoulders braced, and the arm on the operators side is fixed along side the patient. Additionally for hysterectomy the legs are abducted and the buttocks are at the edge of the table to allow easy manipulation of the uterus and access to the rectum. (Bruhat et.al., 1992).

Insufflation

Insufflation is achieved by inserting a Veress needle into the peritoneal cavity, and filing the cavity with carbon dioxide (Figure 1, p17). To safely achieve insufflation the surgeon performs the following steps:

- An insertion site is selected. The subumbilica site is most commonly chosen. If there are suspected adhesions, or abdominal scars from previous surgery, ultrasonic examination of the abdominal wall is performed. This will enable diagnosis of a structure attached to the peritoneal facia. If adhesions are found then another insertion site is selected (Cuschieri, and Berci, 1990).

- A small skin stab wound is made using a scalpel. The incision is large enough to accommodate the endoscope cannula (usually 10mm), and only penetrates through the skin.

- The needle is gripped 30mm from the tip, and inserted into the skin incision at a typical angle of 30° and pushed through the abdominal wall using force applied by the wrist (Figure 21). The fingers positioned near the tip prevent over penetration of the needle (Clover, et.al., 1992). As the point emerges from the abdominal wall and enters the peritoneal cavity, the click of the safety shield covering the needle point should be felt (Cuschieri, and Berci, 1990).

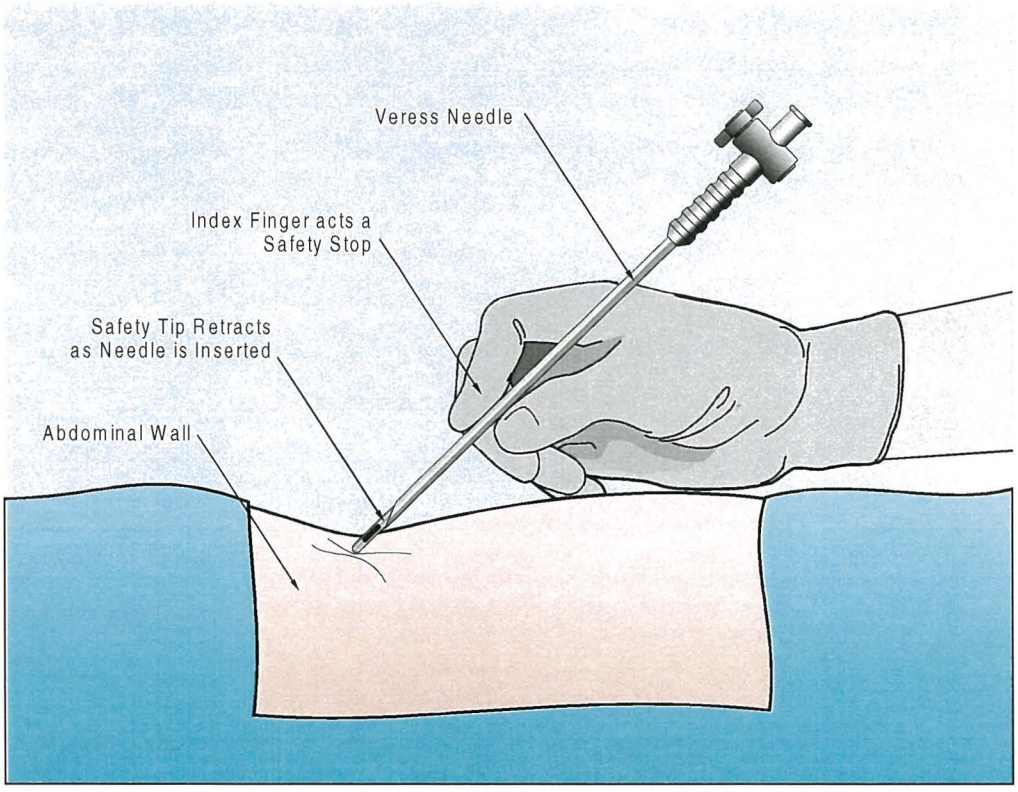


Figure 21 Insertion of the Veress Needle.

- The correct position of the Veress needle is confirmed by a typical injection / aspiration test (Cuschieri, and Berci, 1990). A syringe of saline solution is injected down the Veress needle. If the needle is in peritoneal space then it will be impossible to aspire any saline solution back into the syringe.

- The Veress needle is connected to the insufflator and gas is injected at a low rate of 1l/min. Initially the intra abdominal pressure does not rise appreciably (3mm Hg). An incorrectly placed needle will result in a high pressure reading on the insufflator (Cuschieri, and Berci 1990). Once the abdomen reaches the preset intra-abdominal pressure (12-14 mmHg), the insufflator can be switched to a high flow setting (Bruhat et.al., 1992).

First Trocar Entry

Following the establishment of pneumoperitoneum, the first trocar is introduced, allowing introduction of the camera to the peritoneal cavity (Figure 22). The following steps are performed:

- The insertion site is confirmed after pneumoperitoneum, typically by a sounding test. (Correctly drumming a finger against the abdominal wall).

- Similar to the Veress needle, the trocar is gripped approximately 30mm from the tip. The wrist is used to apply pressure and the fingers act as a safety stop. (Figure 22)

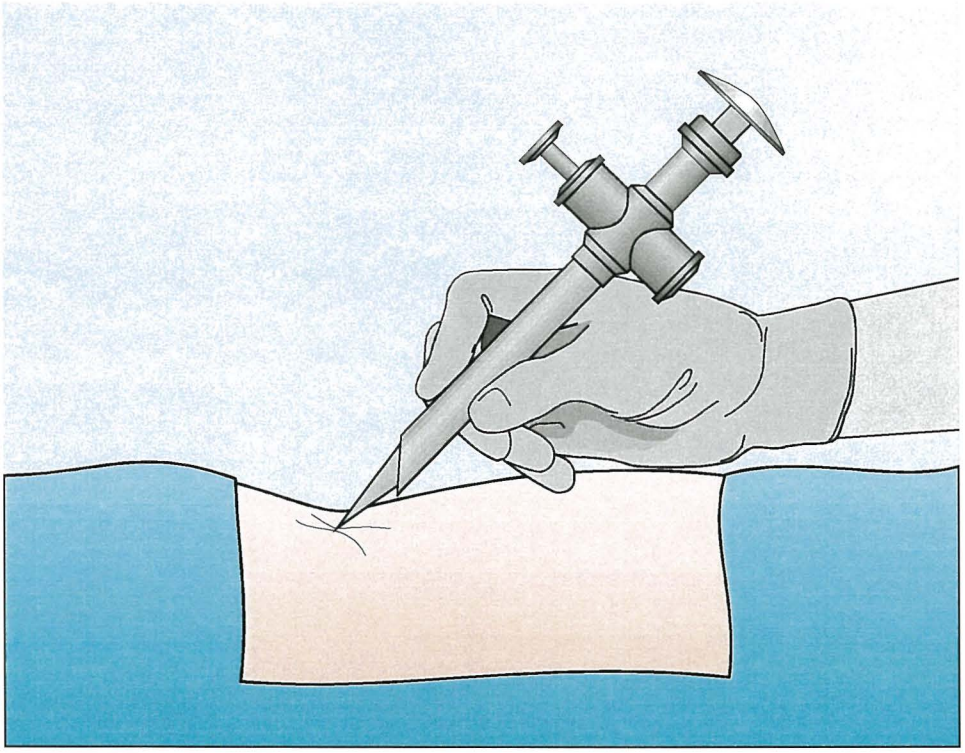


Figure 22 Insertion of the First Trocar.

- The trocar is pushed through the abdominal wall as the trocar penetrates the peritoneal facia, the safety mechanism clicks forward and covers the blade.

- The laparoscope is introduced and the peritoneal cavity is checked to confirm safe entry.

Following the insertion of the first trocar, additional trocars are inserted under direct visualisation from inside the peritoneal cavity (Bruhat et.al., 1992).

With the establishment of a safe pneumoperitoneum, the necessary surgical treatment is performed. At the completion of the treatment the wound are closed.

Wound Closure

Once all bar one of the ports have been removed, all of the gas is evacuated through the final cannula. This is to avoid post operative chest pain. Any residual CO_2 in the abdomen moves upwards and irritates the diaphragm when the patients sits upright. Small amounts of CO_2 are invariably trapped , these are absorbed over the following twenty four hours.

The small incisions of laparoscopy mean that suturing is not always required. When needed, an absorbing, subcuticular suture is used (Figure 23).

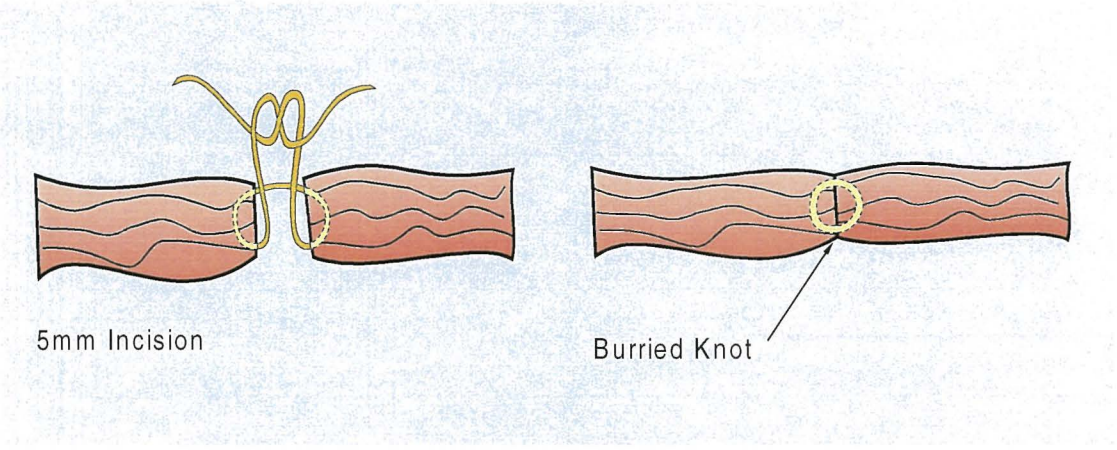


Figure 23 Methods for Wound Closure.

Following laparoscopy non strenuous activities are resumed in 24 hours, and strenuous activities are gradually performed after 72 hours (Hulka, 1985).

2.6.2 Laparoscopic Appendectomy

Diseases of the appendix are very common, making appendectomy one of the most frequently performed operations (Green, and Ponsky, 1994; Zucker, 1991). Definite diagnosis of appendicitis is difficult for the physician as abdominal pain can be attributed to almost any acute process that might occur within the abdomen.

The cause of the disease is typically the existence of an obstruction within the appendix. This obstruction causes swelling and inflammation of the appendix.

Procedure

The basic technique to remove an appendix is performed in four stages (Figure 24).

1. Bi Polar forceps are used to coagulate and dissect the connective tissue film (Mesentery) between the large intestine and the appendix.
2. Sutures are used to tie off (ligate) the base of the appendix in preparation for dissection.
3. The base of the appendix is dissected using hook scissors, thereby totally disconnecting the appendix from the patient.
4. The dissected appendix is removed out through a large cannula.

Patient Recovery

A skilled surgeon performs the operation in 15-20 minutes (Pier et.al., 1993). The majority of patients are discharged on postoperative day one or two, and return to normal activity within one week (Cox et.al., 1993; Fritts and Orlando, 1993; Ludwig, et.al., 1993).

In situations when the appendix is removed using an appendix extractor (typically 20mm diameter trocar) or an extraction bag out an enlarged incision the average hospital stay is increased to 3-4 days, equivalent to the hospital stay for an open appendectomy (Feldman, 1993; Ludwig, et.al., 1993; McArena, et.al., 1992; Suzuki, et.al., 1993; Trias and Targorona, 1994; Zucker, 1991). There are two general reasons for the increased hospitalisation: firstly, the excessively swollen appendix reflects a higher severity of infection and patient illness, and secondly, the larger abdominal wall incision increases the trauma caused by the actual surgical treatment.

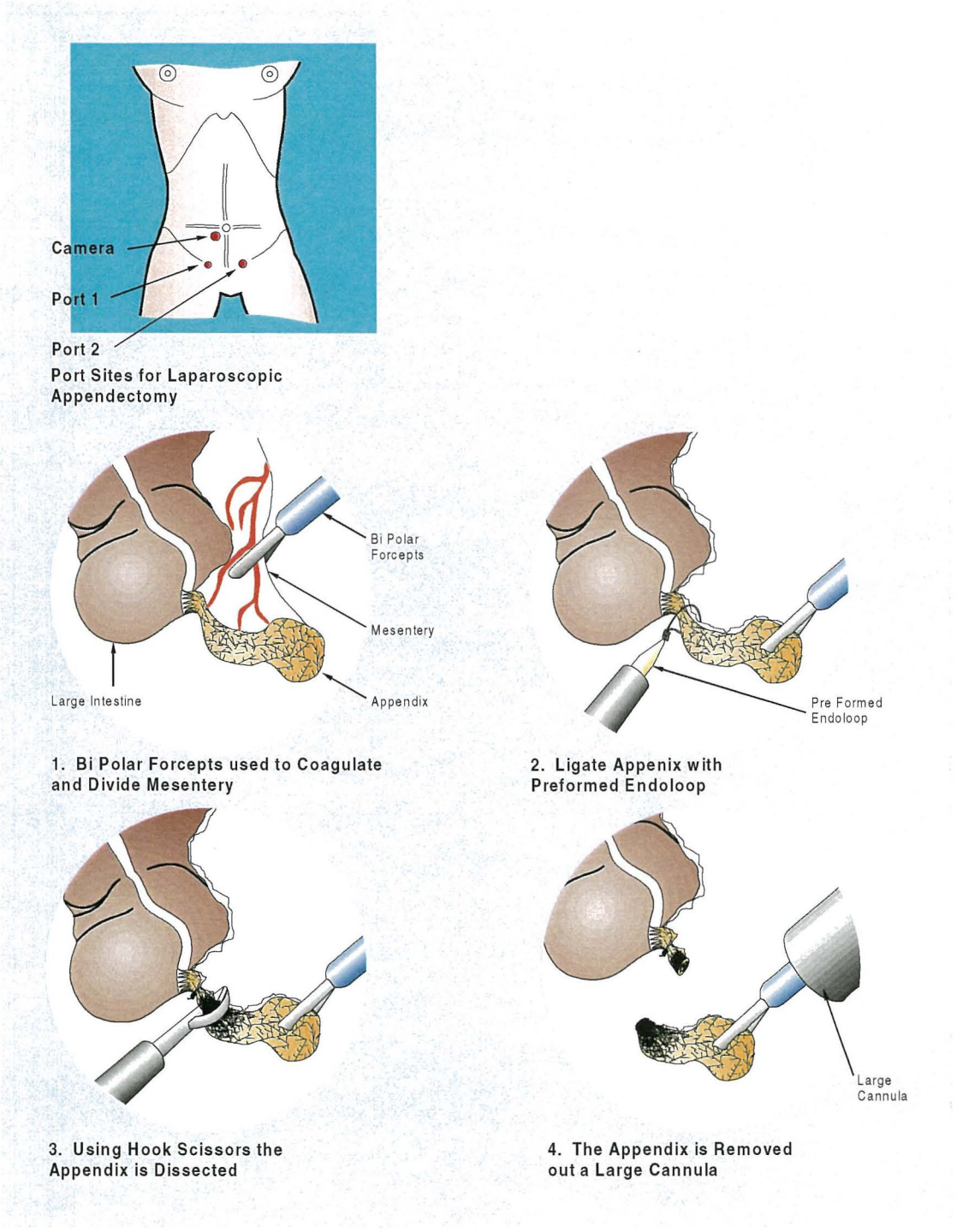


Figure 24 Laparoscopic Appendectomy Sequence of Steps.

2.6.3 Laparoscopic Splenectomy and Nephrectomy

Laparoscopic Nephrectomy and Splenectomy refer to extraction of the spleen and kidney respectively. The steps required to extract a spleen or a kidney are very similar once the organ has been mobilised. For this reason the

details of laparoscopic nephrectomy and splenectomy have been combined into one section.

Patients can be referred for splenectomy for a variety of reasons ranging from immune system disorders to tumour growth. What is most relevant for this research is the physical characteristics of the spleen. Presented spleens can be soft , inflamed, or contain sinus tumour growth.

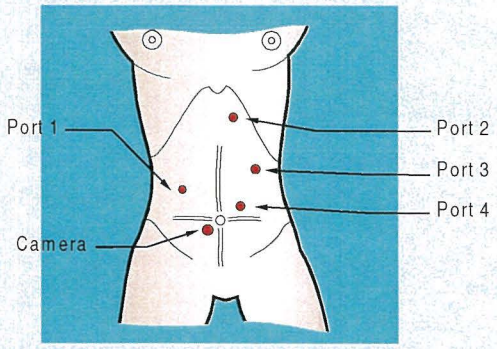
Similarly to laparoscopic splenectomy, laparoscopic nephrectomy is performed to treat a variety of kidney ailments. The presented kidney may contain malignant carcinoma, fibrous polyps, or even a stone.

Procedure

Typically five access ports are established (Figure 25) (McDougall, et.al., 1993). The organ is mobilised from connecting tissue and vascular structures using staples, ligatures, and dissection techniques. The specimen is grasped at the vascular members and manoeuvred into a retrieval bag. The neck of the bag is exteriorised out the 12mm trocar incision. The tissue mass is morcellated by one of a variety of methods (Sections 3.1, p85, and 3.2, p96 contain specific details). Most commonly, the surgeon breaks the organ into large fragments using his / her fingers or blunt nosed forceps. The large morsels are removed from the bag and placed into a receptacle. The extraction bag and remaining contained tissue are withdrawn out through the incision.

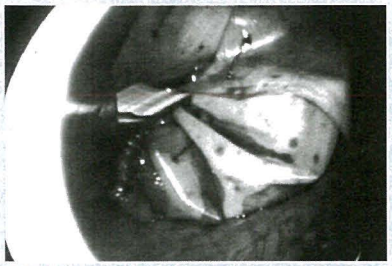
Patient Recovery

Depending upon the nature of the disease, a splenectomy takes approximately 3-4 hours, and patients are discharged on the second or third postoperative day (Cuschieri, et.al., 1992a; Gaur, et.al. 1993; Suzuki, et.al., 1993; Trias et.al., 1994; Tulman, et.al., 1993). Operation time for laparoscopic nephrectomy varies from 6-8 hours, with patients being discharged 5-7 days after the operation, and resuming normal activities in 2-3 weeks (Kerbel, et.al., 1993; Koyle et.al., 1993; McDougall, 1994; Ono, et.al., 1993).



Port Sites for Laparoscopic Splenectomy

1. Inserting an Encapsulation Bag down the Cannula.



2. Encapsulating the Organ.

3. Extracting the Specimen out an Enlarged Incision.

Figure 25 Laparoscopic Nephrectomy / Splenectomy.

2.6.5 Laparoscopic Cholecystectomy

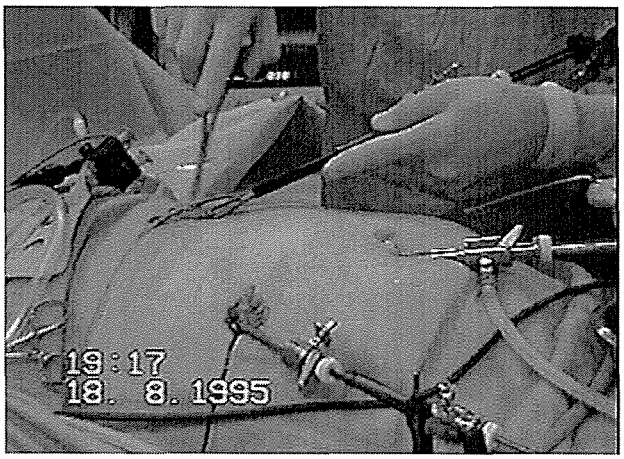
Approximately 10% to 20% of the adult population has gallstones. (McIntyre et.al., 1992). Although the figure remains controversial approximately 20-50% of this population develop symptoms and require treatment. This has lead to over 500 000 cholecystectomies being performed annually (Cagir et.al., 1994; Miller, et.al., 1991).

Gall bladder disease is treated by a variety of methods. Some of the possible treatments include dissolution using acids and contact solvents, Blasting and disintegration using shock wave therapy, or extraction of the gall bladder. A gall bladder is a hollow sack of skin containing fluid. The gallstones which form within the organ are numerous, and can be as large as a jelly bean.

Procedure

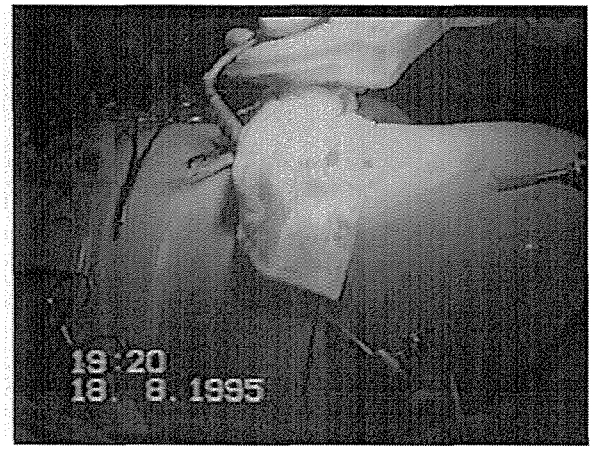
Typically four access ports are used. The cystic duct and artery are clipped and dissected. Using dissection techniques, the gall bladder is mobilised from connecting tissue. Forceps are used to grasp the neck of the gall bladder, and drawn up into the 10mm port. The port is removed and the neck of the gall bladder remains exteriorised from the patient. Before the gall bladder can be totally delivered, the internal stones and fluid have to be aspired. Irrigation equipment will remove the fluid, and forceps are employed to evacuate or crush the stones. Once the contents of the bladder is emptied, it is totally removed from the patient. Figure 26, illustrates the procedure of gall bladder removal.

1. Resection of Connective Tissue and Vessels.



2. Exteriorising the Neck of the Gall Bladder to Remove / Suck Out the Contents.

3. Internal View of Gall Bladder During Removal of Contents.



4. Final Removal of the Empty Gall Bladder.

Figure 26 Removal Of Gall Bladder.

Patient Recovery

A cholecystectomy takes typically 80-100 minutes. Patients are discharged 2-3 days postoperatively, and resume normal activities within one week. (Conway, 1993; Glinatsis, et.al., 1992; McIntyre, et.al., 1992; Paolucci, et.al., 1995).

2.6.6 Laparoscopic Treatment to Female Reproductive System.

Diseases of the female reproductive system are very common. Diseases can range from minor infections to massive malignant tumorous growths. A patient may be required to have cysts, fibrous growths, or ovaries removed, in severe cases the entire uterus and cervix may be extracted.

Specimens extracted from the female reproductive system can be fibrous, or soft and easily ruptured (Hasson, et.al., 1992). It is for these reasons that this section has been included in the thesis. The following paragraphs outline laparoscopic hysterectomy.

Procedure

A patient may be referred for hysterectomy for any one of a large number of different pathological situations. Depending on the extent of the disease the uterus alone may be removed, or the uterus and the cervix may both be extracted.

The basic procedure involves dissecting the falopian tubes, and other connecting vessels from the uterus and the cervix. The cervix is separated from the vagina. Depending upon the physical status of the patient, the mobilised uterus and cervix may be extracted out an abdominal incision or through a vaginal incision (Healy, 1997).

Patient Recovery

Due to the enormous variety in disease and severity of illness, there is an equally large variation in post operative recovery time. There is however consistent additional trauma caused by the abdominal or vaginal incision required to extract the large tissue mass (Boike, et.al., 1993, Jones, 1993a).

2.7 Thoracoscopic Procedures

The following section outlines thoracoscopic procedures. Specifically the initial manoeuvres associated with thoracoscopy are described, and the technique for extraction of a mediastinal mass is discussed.

Unlike laparoscopy, the size of cannula used in thoracoscopy, is restricted to 10mm. This restriction is due to the limited available intercostal space. It is physically impossible to force a 15mm cannula between two ribs that are only 10mm apart (Matar, 1994).

To increase intercostal space beyond 10mm, an incision is made between two adjacent ribs. A spreading vice is inserted into the incision, and force applied to open up the ribs. The process of rib spreading is very traumatic and substantially affects recovery periods (Matar, 1994).

Similar to thoracoscopic surgery, the restriction of cannula size to 10mm is applicable in paediatric surgery for two reasons (Borzzi, 1994):

1. The incision sizes associated with traditional open paediatric surgery are substantially smaller than the adult counterpart, therefore similarly smaller cannula are preferred.

2. A child's viscera are much smaller than the internal organs of an adult, therefore the surgical instruments used on children are smaller. The smaller instruments utilised for paediatric surgery only require small access ports such as 10mm.

2.7.1 Initial Manoeuvres

As with laparoscopic surgery, thoracoscopic operations have a standard sequence of preliminary steps, and closing manoeuvres. The patient is anaesthetised, and his/her breathing is controlled using one lung ventilation. The patient is positioned appropriately and the first incision is made. The closing steps of thoracoscopy are very similar to laparoscopy, the only difference is the absence of desufflation of CO_2.

Patient Position

Patients are positioned in such a way as to obtain maximum intercostal space (Matar, 1994). This is achieved by laying the patient on his/her side with an arm abducted. Maximising intercostal space improves the ease of which instruments can be inserted and removed from the patient.

First Incision

The surgeon performs the following sequence to gain entry to the chest cavity:

- The lung on the operative side is collapsed. This provides space for the surgeon to work in, and prevents possible damage to the lung from the initial incision.

- A small incision is made in the skin using a conventional scalpel.

- Using electrocautery equipment and a scalpel the surgeon penetrates into the pleural space. By inserting a finger into the space, the surgeon confirms penetration.

- A valveless cannula is inserted into the cavity and the scope is introduced. The cannula does not have valves because unlike laparoscopy, there is no insufflation gas, and the operative site is not pressurised. Cannula are still used to reduce trauma at the incision site caused by the insertion, extraction, and movement of instruments through the wound.

- As required, additional incisions are made under direct visualisation using trocars.

2.7.2 Mediastinal Masses

A mediastinal mass constitutes an abnormal growth in the mediastine (the internal wall of the chest cavity). Masses can be composed of fibrous material or liquid ooze. The growths can be benign or malignant (Kaiser, and Daniel, 1993).

Procedure

The mass to be removed is examined upon penetration into the mediastine. Using dissection techniques the mass is exercised from the chest wall (Figure 27). If vascular structures are encountered they are clipped or dissected using electrocautery equipment. Providing the mass is not too large it is removed out the cannula. Large masses are extracted out a thoracic incision. Rib spreading devices may be required to obtain sufficient intercostal clearance (Matar, 1994).

Patient Recovery

Operation times vary depending upon the size, number of, and accessibility of the mass/es. Patients who suffered no incision enlargement are typically discharged 3-5 days postoperatively, and resume normal lifestyle within 10-14 days (Landreneau et.al., 1992). Patients who required mini-thoracotomy encounter substantially added trauma from the large incision. Hospital discharge occurs 10-14 days postoperatively, and full recovery extends over a period of months. (Cuschieri et.al., 1992b).

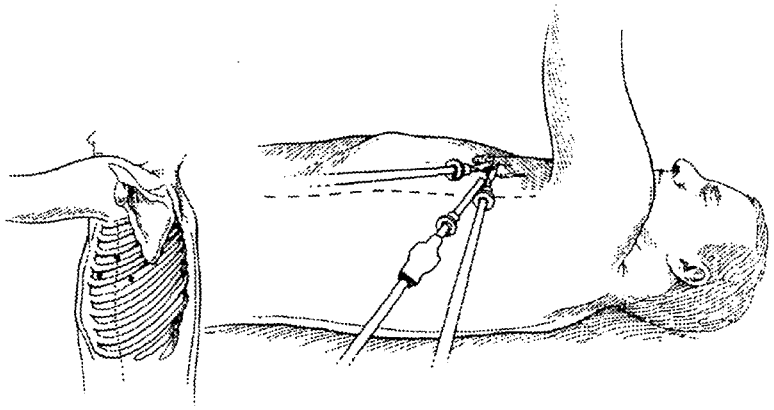


Figure 27 Endoscopic Removal of Mediastinal Mass.

(Pearson, and Griffith, 1995)

2.8 Design Issues in Endoscopy

The specific conditions under which endoscopy takes place, has had a direct impact on the associated instrument design. Instruments have to be considered as remote handling devices, thus perception, orientation and control issues have become more significant than with past implements (Cuschieri, and Berci, 1990; Hirsch, and Hailey, 1992; Riemann, 1993).

The rapid adoption of endoscopy by surgeons has called for new educational techniques to cope with the increased diffusion of knowledge, in a limited time (Hirsch, and Hailey, 1992).

Small complex mechanisms are very difficult to adequately clean, sterilise, and maintain (Hirsch, and Hailey, 1992). Many endoscopic instruments are small and intricate. In response to this there has been an overwhelming number of disposable devices made available in the last five years. Cost issues have to be considered when selecting and designing either disposable or reusable equipment.

2.8.1 Hand and Instrument Interaction / Co-ordination

In traditional surgery the surgeon could look directly upon, and feel with his/her hand the tissues he/she was manipulating. Endoscopic surgery has, moved the visual field to the television monitor, eliminated the possibility of directly feeling internal tissues, and shifted all instrument controls thirty-five millimetres back from the operative spot (Satava, 1993). In combination, these three factors are perhaps the biggest hurdle faced by surgeons learning endoscopic surgical techniques. (Cuschieri, and Berci, 1990; Williams, 1994).

All manipulation instruments are operated in combination with a surgical port or access cannula. To ensure that an instrument can reach all the required positions and locations within a patient, implements have a shaft of 350mm. The long span separates the surgeons hand from the active point of the instrument. The large separation increases the difficulty of performing any instrument manoeuvres (Bruhat et.al., 1992; Cuschieri, and Berci, 1990).

As a direct result of the long, thin instrument shafts, a second problem, is the loss of leverage about a hinge point. The mechanics are restricted to working within the small diameter of the cannula.

Overall the loss of direct tissue contact, an inability to apply large forces, and reduced instrument control significantly reduce the confidence of the physician. With training and extensive experience, a surgeon becomes more comfortable with the technique, however the underlying problems always remain (Cuschieri, and Berci, 1990).

2.8.2 Depth and Position Perception

Depth and position perception refer to the ability to accurately understand the planar position of an instrument in relation to its surrounding. Endoscopic surgery has forced surgeons to become accustomed to a flat two dimensional world represented on a television screen, thus removing any sense of depth within the field of view (Cuschieri, and Berci, 1990). Essentially the technique has removed the operators natural stereoscopic visual capabilities, Operating via a television monitor, is comparable to operating with one eye closed.

This inability to immediately recognise the operative plane is the source of many surgical errors. These errors range from very minor mistakes, for example an incomplete tissue cut, to major problems, such as a large vessel laceration.

In attempt to address this problem, three dimensional stereoptical visualisation systems are under development. The systems utilise an endostereoscope. The two images generated are processed by a computer and alternately transmitted to a television screen, at a very high switching rate. The surgeon wears polarised eye glasses that are synchronised to the switching rate of the television monitor, using an infra red transmitter (MacFadyen, 1992). Although still in prototype stage, this system is expected to make endoscopic surgery much easier to learn and perform, improving surgeons confidence and operative speed (Silbertrust, 1993).

2.8.3 Orientation

Orientation refers to the process of determining the directional position of an object relative to its surroundings. Correct assessment of orientation allows controlled movement in a desired direction, without becoming lost or unsure of the path being undertaken.

Endoscopic surgery has separated the surgeon from the instrument. The instrument controls have been separated from the active operative area. The surgeons eye no longer looks directly at the operative site. Essentially all the connections, bar the two dimensional television image, between the surgeons hand and the surgeons eye have been eliminated. The result is a significant loss of orientation.

The camera is operated by the surgeons main assistant (usually a doctor doing his internship). The two main aims of the operator are to: (1). Keep the camera focused on the active area, and (2). To always have the posteria of the patient toward the bottom of the television image.

A solution to the orientation problem is being investigated in the area of virtual reality (Satava, 1992). Using glasses, and visual projection systems employed in aircraft fighter pilot helmets, a surgeon may be able to look directly at the operative site, and have the internal images superimposed, such that the patient appears transparent (Beer-Gabel, Delmotte, and Muntlak, 1992).

2.8.4 Training in Endoscopic Surgery

The unprecedented, rapid development and widespread use of minimal access surgery caught surgeons and associated industry by surprise (Cuschieri, et.al., 1992b; Poole, 1993). The benefits associated with endoscopy, induced substantial media attention and public demand for the adoption of the new techniques. As a result of the intense interest, experienced and new surgeons alike have been required to learn and begin utilising the minimal access approach.

The large number of physicians wanting to learn and practise the new technique, has required the adoption of equally new teaching and training methods (Poole, 1993).

Conventional Surgical Training

Training for conventional surgery was based on a residency program, not unlike a master / apprentice, system. Resident surgeons follow a rotational observation and participation programme. The student initially observes procedures, and as time goes on begins helping with the minor steps of the procedure. Such tasks may include holding retractors and forceps. As the resident gains experience their involvement in the operation escalates to the point where they eventually perform the entire operation under the appropriate supervision (Cuschieri, Buess, and Perissat, 1992; Dent, 1993).

Training techniques such as these are highly effective at producing capable, and to a certain extent, experienced physicians (Bernard, 1993). One significant disadvantage of the residency method of training is the substantial time and resources required to educate a new resident surgeon (Cuschieri, Buess, and Perissat, 1992).

Training for Endoscopic Surgery

The pressure from patients for the adoption of endoscopic techniques has demanded training methods which enable a more rapid process. As an initial response to the demand, industry set up training programmes and seminars. Between 1992 and 1995 these training schools have been expanded, and typically are situated in a recognised surgical training centre with backing from a medical corporation.

Endoscopic training consists of a series of exercises conducted on mock up patients. The exercises address the handling and surgical techniques unique to endoscopy (Cuschieri, 1992). The teachings serve as an addition to the extensive knowledge gained through traditional operative training. Physical exercises are conducted to prepare the surgeon for the unique circumstance and user problems encountered with scopic operations such as:

- The initial manoeuvres including pneumoperitoneum and trocar insertion.
- Working with small diameter implements with long operating shafts.
- Lack of tactile feedback and direct access to the operative site.
- Overcoming the orientation and perception problems of operating from two dimensional image (Cuschieri, Buess, and Perissat, 1992).

When a manufacturer releases a new product onto the market, the correct use of the new implement is taught in two ways.

1. The physician attends demonstration seminars conducted by the implement supplier. The surgeons are shown in detail the proper use of the presented device, and discussion is held on any issues relevant to the adoption of the new piece of equipment.

2. The supplier of the implement may send a consultant to the operating theatre to aid the surgeon and supervise the use of the device. The consultant will have had extensive experience with the new device, and be able to discuss any problems or issues which may arise throughout the procedure.

As endoscopic surgery becomes more widely practised, and the international standard in operative treatment, the pressure on intensive training centres will decrease and shift again toward the master / apprentice system of education (Cuschieri, Buess, and Perissat, 1992).

2.8.5 Instrument Cost Issues in Endoscopy

The adoption of minimal access surgical techniques has instigated the development of a huge range of disposable and reusable instruments. An issue currently under debate within the medical and associated technology industry, centres around the cost and environmental considerations when choosing between a single use product or a reusable device (Estrin, 1990; Hirsch, and Hailey, 1992; Reichert, 1993). The fundamental deciding factor between any two instruments is the quality of patient care achieved at an acceptable cost (Weatherly, and Young, 1994).

The advantages of disposable devices over reusable devices include:

- An instrument almost never becomes dull or jams, failing in the middle of an operation.
- The elimination of possible leaks or broken seals from repetitive cleaning and sterilisation.
- Adequate cleaning becomes irrelevant, and sterility is guaranteed.
- Problems associated with disassembling and reassembling implements are avoided.
- There is no possibility of losing product components.

- Direct and indirect costs associated with cleaning, sterilisation, storage, handling, maintenance, and use of expendable resources are eliminated.
- Elimination of instrument availability and processing turn around problems.

The only significant disadvantage of using a disposable device is the environmental considerations. All medical waste is incinerated. Single use devices require the continual consumption of materials and energy for production and disposal.

Advocates of disposable equipment, argue the cost of handling reusable instruments and achieving an acceptable level of care quality, generates excessive costs (Reichert, 1993; Weatherly, and Young, 1994). Advocates of reusable technology argue the environmental cost, and purchasing costs of disposable equipment to be exorbitant and unacceptable (Daniel, 1993).

Evaluation studies have been conducted which aim to examine quality and cost variables associated with using either reusable or disposable instruments, in similar operative situations (Reichert, 1993; Weatherly, and Young, 1994). The studies attempt to establish quantitative data to compare the two instrument categories, but It seems they fail to obtain adequately accurate figures for three reasons:

1. Accurately monitoring or estimating the cost of using a reusable device over the products entire life is difficult, if not impossible. The large number of small expenses incurred while using a product are very difficult to formulate into a quantitative figure (Estrin, 1990; Jones, 1993b). These small expenses include:

- The cost of training existing nursing staff to adequately clean, disassemble, reassemble, sterilise, and handle the device.
-The cost of training any new staff which have to be educated to process the implement.
- Decontamination process costs. These costs refer to all costs incurred when cleaning the apparatus after it has been used.
- Inspection and maintenance costs of keeping an instrument functioning properly.
- Sterilisation costs.
- Stock control and inventory costs.

2. No attempt is made to quantitatively assess the environmental impact of using the different instruments (i.e. reusable or disposable). The environmental cost of using a product begins at the extraction of raw materials for production, and finishes at the disposal and decomposition of the product back into the environment. As defined by the EcoRedesign Centre for Design at RMIT (Gertsakis, 1993), environmental costs can include:

- The environmental cost of obtaining a raw material, and processing the substance into a useful state.
- The expenses associated with converting a processed substance into manufactured, saleable instrument.
- The cost of the water and chemicals used to clean and manufacture an instrument.
- The financial and ecological cost of disposing of an instrument.
- The quantity of non-renewable resources consumed to supply electricity to the manufacturing and re-use of a product.

3. The political and commercial interests of parties involved in the conduct of comparative studies has to be examined. Many hospitals and educational institutions receive substantial financial support from manufacturers of medical equipment. It would be safe to assume that such institutions are more likely to produce recommendations in favour of the medical company providing support. Evidence of this is shown in the wide range of opinions published and proclaimed throughout the medical industry (Nathansen, 1995; Estrin, 1990; Fielding, 1994; Reichardt, 1993; Weatherley, and Young, 1994).

The physical size restrictions placed on endoscopic instruments has resulted in products which have intricate and extremely complex mechanics. To make instruments such as complex staplers, reusable, is simply not possible due to the small and extremely intricate mechanisms contained within each device. However, on less mechanised products such as lavage handles, a compromise can be met, in a disposable product intended for limited reuse. The handle in Figure 28 has been designed to be reused five times. The instrument goes through five cycles of: use, cleaning, and re-sterilisation. For these five procedures the operational quality and reliability can be

guaranteed. The cleaning and re-sterilisation process is very hard wearing and stressful on the instruments. Therefore after being reprocessed and reused five times, the correct operation of the instrument cannot be guaranteed, thus it is disposed of.

Figure 28 Limited reusable Lavage Handle.

(UniSurge, 1993)

For the designer, the appropriate "cost" decisions will be centred around both - the total physical requirements (this includes: user needs, functional constraints, and production criteria) of the proposed product, and the directives of the marketing department of the manufacturer.

2.9 Summary

Chapter 2 provides knowledge based upon which the analysis into tissue extraction in endoscopy (Chapter 3) can proceed. The knowledge presented in Chapter 2 described the contextual environment of the endoscopic operating theatre. The surgical procedures particularly relevant to organ extraction at endoscopy have been outlined. Design issues, specifically associated with endoscopic surgery were discussed.

The research established in Chapter 2, combined with the results of the analysis outlined in Chapter 3, is used to initiate the design criteria checklist described in Chapter 4.

CHAPTER 3

Organ Extraction in Endoscopy - An Analysis

"Surgery does the ideal thing - it separates the patient from his disease. It puts the patient back to bed and the disease in a bottle." (Logan Clendening).

An important part of the design process is to learn from others. Through the study of previous works, the possibility of repeating mistakes previously made by others is reduced.

This chapter is an analysis of the current status of organ removal in endoscopy. Three specific areas are analysed and documented:

- Tissue Extraction Techniques used by surgeon.
  The three general techniques for extracting an organ in endoscopy are compared.

- Instruments for Tissue Endoscopic Tissue Extraction.
  Five instruments are available for the facilitation of tissue extraction in endoscopy. Each of the instruments utilises one of the three general extraction techniques.

- Tissue Retrieval Bags used for Endoscopy.
  Tissue retrieval bags are used in combination with many of the endoscopic tissue extraction techniques. A selection of available tissue retrieval bags are documented and described.

The conclusions of the following analysis are used in conjunction with the initial research conducted in Chapter 2, to form the basis of the design criteria checklist for an endoscopic tissue extraction device (Chapter 4, p121).

3.1 Analysis of Tissue Extraction Techniques

The three basic techniques for removing a large tissue specimen from a patient undergoing endoscopy are:

- Enlarging one of the established trocar wounds and pulling the specimen out the incision.
- Removing the organ or tissue via an extra large cannula (diameter 20-30mm).
- Morcellating the specimen into smaller tissue fragments suitable in size to be removed through existing cannula or trocar incisions.

An analysis is conducted of these three methods to establish the most promising technique for design exploration. The analysis also highlights the strong and weak aspects of each process, enabling recognition of the qualities which can be respectively, utilised and improved by a proposed design.

The method used to compare each of the three techniques is the Ranked and Weighted Objective Method (Jones, 1980; Cross, 1989). The analysis is limited to comparative critique of each of the extraction techniques fundamental characteristics, and in no way aims to examine the equipment used to perform tissue removal.

The following sections describe: The analysis method used, The techniques examined, The actual analysis, An interpretation of the results of the analysis, and conclusions derived.

3.1.1 Analysis Method

The Ranking and Weighting Objective method (Jones, 1980; Cross, 1989) used for the comparison of the three extraction techniques involves:

- Establishing a list of performance objectives for evaluating the success of the technique.

- Ranking these performance objectives in order of importance, and applying a weighting to each of the objectives (1 less important - 10 most important).

- Measuring each technique against the various objectives using as common scale (1 very poor - 5 very good).

- Totalling and analysing the scores.

The outcome provides a measure of the overall extraction technique. The analysis highlights the strong and weak aspects of each technique in a clear numerical manner. The strong aspects of a design receive a high score while the weak aspects receive a low score.

3.1.2 Techniques of Organ Extraction

The three techniques of organ extraction (enlarging incision, large trocar, and morcellation) all have the same aim: to effectively remove a selected tissue specimen from a patient with minimal additional trauma. To assess the extent to which the extraction method satisfies this aim, the steps involved in utilising each technique are studied.

The three extraction methods are all preceded by the following step:

The selected organ is isolated from all other viscera and connective tissues. This is achieved using a variety of dissection, stapling, and clipping manoeuvres. The isolated organ is approximated to an openly exposed location, where it can be easily identified and retrieved from.

Following this, the sequence of operations for each technique are:

Enlarging Existing Trocar Incision

An endoscopic plastic bag is rolled up tight around the top of a pair of forceps and forced down a cannula into the abdominal (laparoscopy) or thoracic (thoracoscopy) cavity (Figure 29).

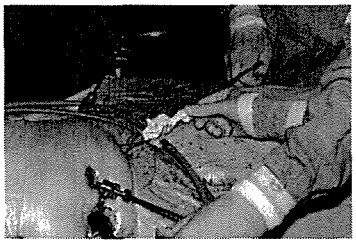


Figure 29 Inserting an Endoscopic Retrieval Bag Down a Cannula.

The bag is unrolled and opened up using forceps. It is held open and the organ is forced inside the sac. Typically the bag is held in a triangular formation and manoeuvred such that it catches the organ like a fishing net (Figure 30a).

Once the organ is inside the bag, then the draw string around the top of the bag is pulled, closing the top of the sac. This prevents the organ from unintentionally falling out of the pouch (Figure 30b).

The top of the bag is grasped with a pair of forceps and pulled out one of the cannula. As the bag is drawn out, the cannula is removed simultaneously, leaving the top of the sac protruding from the skin (Figure 30c).

Figure 30 Capturing the Organ.

(a). Manoeuvring the Organ into the Bag. (b). Closing the Bag. (c). Removing the Cannula.

Using a guard and scalpel the surgeon enlarges the 10mm trocar wound to a 50-60mm incision. The exact size of the incision varies with the size of the organ being extracted (Figure 31a).

The surgeon grips the top of the bag and applies a large force, pulling the bag and contained organ out the incision. An assistant applies pressure with retractors to hold the incision open and aid the removal process (Figure 31b).

The extracted organ is emptied from the bag into a kidney dish and then into a plastic container and sent to pathology (Figure 31c).

Figure 31 Removing the Organ.

(a). Enlarging the Incision. (b). Extracting the Organ. (c). Extracted Organ in the Kidney Dish.

This process of extraction allows a specimen of any size to be removed from the patient. Extra costs are minimal as the only additional equipment required is a strong impermeable plastic bag. The ability to maintain a pneumoperitoneum is severely compromised as insufflation gas will escape out the large incision (Childers, 1993).

Enlarging of the trocar incision adds considerably to the operational trauma (Bickel, et.al., 1993; Kanehira, et.al., 1994). In laparoscopic procedures, the extra incision (often referred to as mini laparonomy) will lengthen a patients postoperative hospital stay to 5-7 days, and prevent their return to normal lifestyle for 2-3 weeks (Kerbel, et.al., 1993). In thoracoscopic operations, the extra incision (mini thoracotomy) will lengthen the hospital stay to 10-14 days, and complete return to normal lifestyle will take several months (Matar, 1994).

Extracting Through a Large Trocar

One cannula is selected as the extraction site. A guide rod is inserted down the 7-10mm cannula. The cannula is removed leaving the guide rod in the incision. The skin incision is slightly extended with a scalpel. A dilatation trocar inside a 20mm cannula is passed over the guide rod. Using steady pressure and a turning motion the dilatation cannula is passed through the facial into the operational cavity. The dilatation trocar and guide rod are then removed, leaving the 20mm cannula in place (Cuschieri, Buess, and Perissat, 1992). This is illustrated in Figure 32.

Once the 20mm cannula has been positioned, forceps are introduced and used to grip the tissue mass for extraction. The mass is pulled up into the cannula and removed from the patient. The specimen can then be placed into a sample jar and sent to pathology for examination.

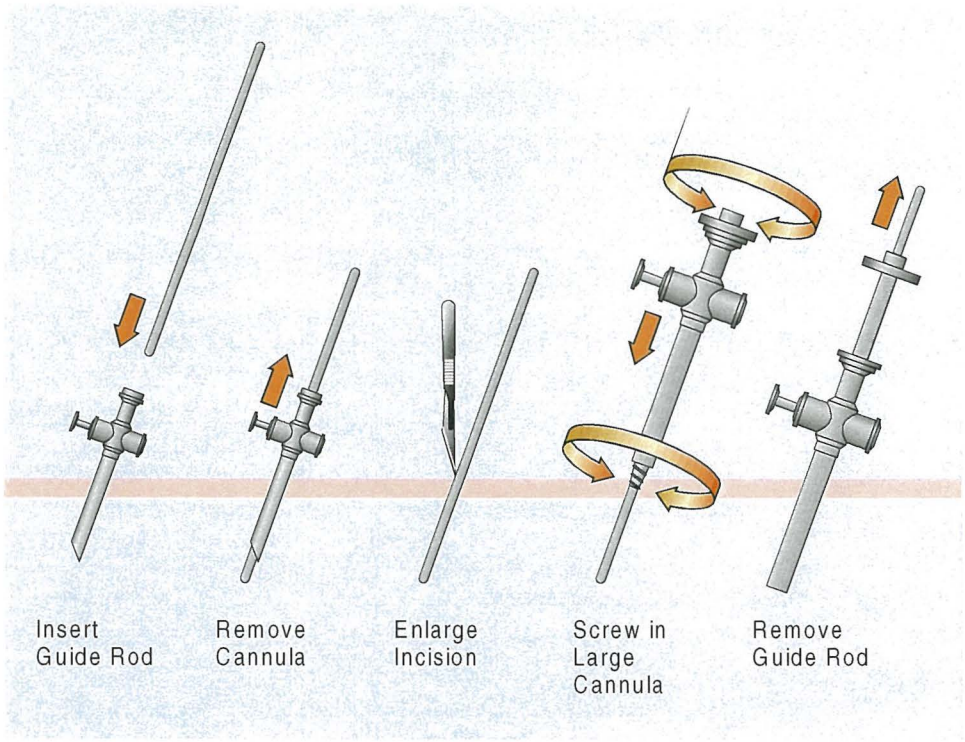


Figure 32 Representation of a 10mm port increased to 20mm.

As this method of extraction uses a defined port dimension, the size of the specimen to be extracted is limited to the diameter of the cannula. Such a restriction severely limits the application of the technique to only smaller specimens such as appendices. The oversized cannula is too large for application in thoracoscopy as the instrument diameter is greater than the available intercostal space (Matar, 1994).

The ability of the technique to contain diseased cells is limited as no encapsulation bag is utilised. Unhealthy tissue can fall back down the cannula into the operative cavity.

An additional cost is incurred in the purchase of the large cannula and dilatation trocar.

The use of a large cannula adds significantly to the trauma caused by surgery. Patients are discharged on postoperative day 3-4, and resume normal activities in 1-2 weeks.

Tissue Morcellation Prior to Extraction.

The morcellation technique of tissue extraction begins in a similar manner to extraction out an enlarged incision. An encapsulation sac is introduced into the patient. The selected organ is manoeuvred into the bag and the mouth of

the bag is exteriorised. Any one of a variety of methods - high speed electric morcellation, finger or manual morcellation is applied to the encapsulated specimen, breaking it down into smaller tissue fragments (Figure 33).

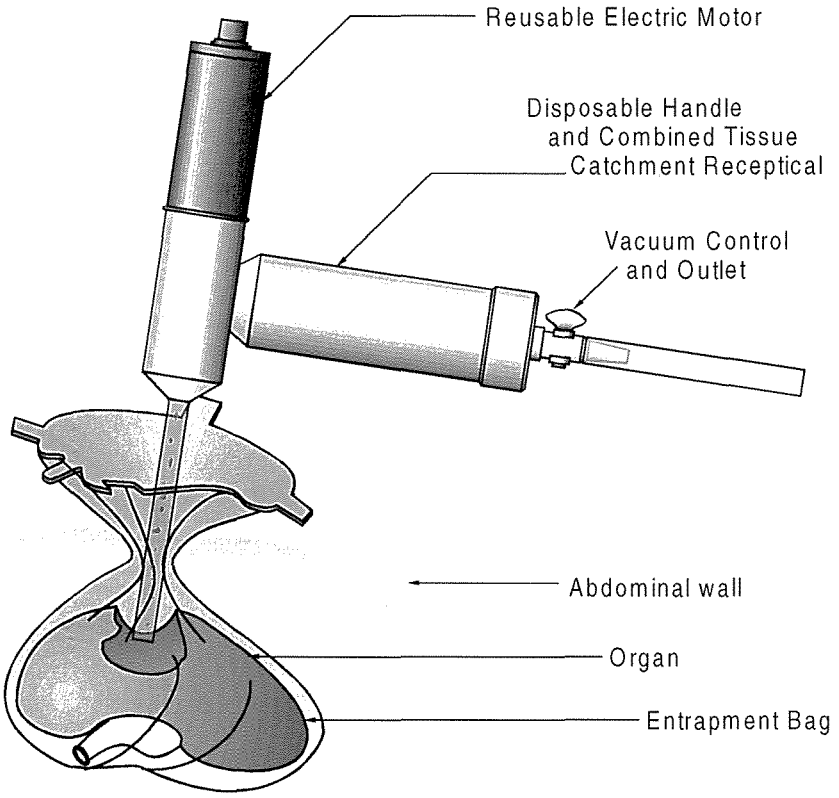


Figure 33 Morcellation Using a High Speed Electric Morcellator.

The resultant tissue fragments are removed out the mouth of the bag without the need to enlarge the trocar incision. The tissue pieces are deposited into a specimen jar and sent to pathology for examination.

The technique of extraction by morcellation can become expensive, depending upon the complexity of the morcellation instruments chosen. The fragmented nature of the retrieved tissue fragments produces a lower quality specimen for pathological examination (Hirsch, and Hailey, 1992, Kavoussi, et.al., 1992).

By using a morcellation technique, no additional therapeutic trauma is incurred. Pending the extent of the illness prior to the operation, patients leave hospital on the 2-3 postoperative day, and resume normal activities within one week.

3.1.3 The Analysis

Eight performance objectives have been established to compare the three extraction techniques. A Matrix is used to compile the objectives and provide an overall analysis of the tissue extraction techniques for endoscopy. The performance objectives identified as being key requirements for the technique to fulfil include :

- Patient and Physician Safety,
- Compromise Endoscopic Approach,
- Contain Disease,
- Function,
- Pathological Requirements,
- Application in Laparoscopy, Thoracoscopy, and Paediatrics,
- Maintain Pneumoperitoneum,
- Additional Cost.

Patient and Physician Safety

Patient and surgeon safety assesses the risk of possible inadvertent injury to patient or physician.

Compromise Endoscopic Approach

Compromise endoscopic approach, refers to the extent of which the benefits associated with endoscopy (Section 1.1, p16), are negated to extract the specimen.

Contain Disease

Containment of disease during the removal process is analysed. Diseased tissues can infect an incision site or cause tumour seeding around the operative site if managed improperly (Cacdac and Lakra, 1993; Kavoussi and Clayman, 1992; Sharp et.al., 1992; Steege, 1994; Tate, et.al., 1993).

Function

Function is a measure of the techniques ability to extract a wide variety of tissues including: fibrous tissue, benign and malignant tumours infected viscera, organs containing stones, large inflamed spleens, and dissected specimens containing staples and clips.

Pathological Requirements

Pathological requirements is the evaluation of the techniques ability to produce an extracted specimen in a condition suitable for examination. Pathologists prefer an organ to be presented as a whole, however the first step they perform in an examination, is to slice the specimen into approximately 10mm strips to provide a series of cross sections.

Application in Laparoscopy, Thoracoscopy, and Paediatrics

Application in laparoscopy, thoracoscopy, and paediatrics, assesses the ability to use the extraction technique in each of the endoscopic disciplines. Laparoscopy poses the least physical limitations. In thoracoscopy, instruments are limited in size by the available intercostal space. Paediatric surgery requires finer instruments to prevent excessive trauma being caused to the physically smaller and more sensitive patients (Borzzi, 1994).

Maintain Pneumoperitoneum

Laparoscopy relies on a pneumoperitoneum to provide the surgeon with visualisation of the operative site. A loss of pneumoperitoneum results in a loss of control.

Additional Cost

Additional cost is a qualitative measure of the expense of purchasing non-standard equipment specifically required to use the chosen technique.

Matrix Analysis of Organ Extraction Techniques

The following matrix (Figure 34), provides an overall analysis of the tissue extraction techniques for endoscopy. To interpret the matrix look at the **Performance Objective** item, then at the **Extraction Technique**. The ability of the selected extraction technique to meet the performance objective is given a score out of five (one being the lowest and five being the highest). The score is then multiplied by the weighting for that performance objective. This process is repeated for each of the performance objectives, A total score for that extraction technique is obtained by adding up each multiplication's.

Weighting	Performance Objective	Extraction Technique		
		Enlarge Incision	Large Trocar	Morsellation
10	Contain Disease	■■■■■	■■□□□	■■■■■
10	Patient and Physician Safety	■■■■■	■■■■■	■■■■■
10	Compromise Endoscopic Approach	■□□□□	■■■□□	■■■■■
8	Function	■■■■■	■□□□□	■■■■■
7	Pathological Requirements	■■■■■	■■■■■	■■■■□
6	Application in Lap., Thorac., & Paediatrics	■■■■■	■□□□□	■■■■■
4	Additional Cost	■■■■□	■■■□□	■■■□□
4	Maintain Pneumoperitoneum	■□□□□	■■■■■	■■■■■
	Total Score out of 295	**235**	**181**	**280**

Legend: ■ = 1, □ = 0, ■■□□□ = 2 out of 5

Figure 34 Matrix Analysis of Organ Extraction Techniques.

Interpretation example: To obtain the score of 235 for the Extraction Technique of Enlarge Incision, the following steps are performed:

- The technique of Enlarge Incision completely satisfies the performance objective of Contain Disease and therefore receives a score of 5 out of 5. The other extraction techniques of Large Trocar, and Morcellation receive scores of 2, and 5 respectively for the same performance objective. (Large Trocar only received a score of 2 because it only partially fulfils the performance objective of Contain Disease).

- Referring again to the extraction technique of Enlarge Incision, the score of 5 obtained for performance objective of Contain Disease is multiplied by the corresponding weighting for that particular performance objective, a value of 10, therefore 5 x 10 = a weighted score of 50.

- This process of multiplying each score (out of 5) by the corresponding performance objective weighting, is repeated for each of the performance objectives. e.g. For the performance objective of Maintain Pneumoperitoneum, Enlarge Incision scores 1 out of 5, x a weighting of 4 = a weighted score of 4. This is repeated for each of the 8 performance objectives.

- The final weighted scores for each performance objective are totalled. Enlarge incision obtained the following weighted scores for each

performance objective - 50 + 50 + 10 + 40 + 35 + 30 + 16 + 4 = a total score of 235. The maximum possible score is 295.

The above described process is repeated for each of the three Extraction Techniques, producing a quantifiable figure to compare each of the techniques.

This technique of analytical comparison is later utilised for the analysis of the instruments used for endoscopic tissue extraction (Figure 42, p111).

3.1.4 Interpretation of Results

All scores and ratings contained in the following section refer to the qualitative results established through the matrix analysis (Figure 34, p93).

The total scores for the three extraction techniques of Enlarge Incision, Large Trocar, and Morcellation received total scores of 235, 181, and 280 respectively. Therefore the analysis of organ extraction methods reveals that the technique of specimen morcellation (receiving the highest score of 280 out of a possible 295) presents the best potential direction for product development. The morcellation technique presents itself as substantially more promising than enlarging an incision (scoring 235), or using a large trocar (scoring 181).

Referring to the matrix (Figure 34, p93), the technique of Morcellation has two weaker aspects; 1. The additional cost incurred by the specialised instruments needed (scoring 3 out of 5), and 2. The poorer quality specimen presented for pathological examination (scoring 4 out of 5).

3.1.5 Summary

The following summations are drawn from the results of the analysis (Section 3.1.4):

The technique of extraction by morcellation is the most promising direction of exploration in the pursuit of effective removal of large tissue specimens at endoscopy.

The cost of using a morcellation device needs to be kept to an acceptable level in light of the perceived benefits of using the technique. If costs appear

exorbitant, any proposed design will be criticised and abandoned as being excessively expensive.

The pathological condition of specimens needs to be of the highest possible quality when extracting out a 10mm surgical port or trocar incision. Pathologists have traditionally been presented with whole viscera for examination. A pre-dissected specimen will produce some anxiety amongst pathologists, however totally obliterated or pureed samples will surely be rejected.

3.2 An Analysis of Instruments for Endoscopic Tissue Extraction.

Several instruments are commercially available for endoscopy tissue extraction. There are also several designs which have been published, documented, and tested as prototypes. An analysis of five instruments and their ability to successfully extract large tissue specimens in endoscopy, is conducted. The analysis outlines the advantages and disadvantages of each design.

Similarly to the previous "Analysis of Organ Extraction Techniques" the Ranked and Weighted Objective Method is used (Section 3.1.1, p85). Assessment of each of the instruments was based upon available literature, and discussions with medical and manufacturing professionals, (as referenced).

The following sections describe: The analysis method used, The implements examined, The actual analysis, An interpretation of the results of the analysis, and Summary.

3.2.1 Analysis Method

The method of analysis used to compare the five extraction implements, involves the same process as used for the examination of organ extraction techniques (Section 3.1.1, p85). The only significant modification to the process is the expansion of the "performance objectives" into a larger list of design criteria.

The outcome of the following analysis demonstrates the successful and unsuccessful aspects of each design (Figure 42, p111).

3.2.2 The Instruments

Five instruments have been selected for analysis. There are three specific reasons for choosing these five instruments for analysis:

1. They are predominantly the more widely used and tested instruments.

2. They are the most extensively published and documented.
3. All five designs are based on a different design concept.

The five instruments are:

- Cook Urological Tissue Morcellator
- Steiner et al. Electrical Cutting Device
- Cuschieri Tissue Slicer
- "Bergetrokar" Large Trocar
- Blunt Dissection using Scissors and Physicians fingers.

Cook Urological Tissue Morcellator

The Cook Tissue Morcellator is a high speed rotary scalpel designed for the dissection and removal of tissue at endoscopy (Figure 35). The device consists of an entrapment bag, a high speed cutting blade, and suction, to remove selected tissue from within the patient.

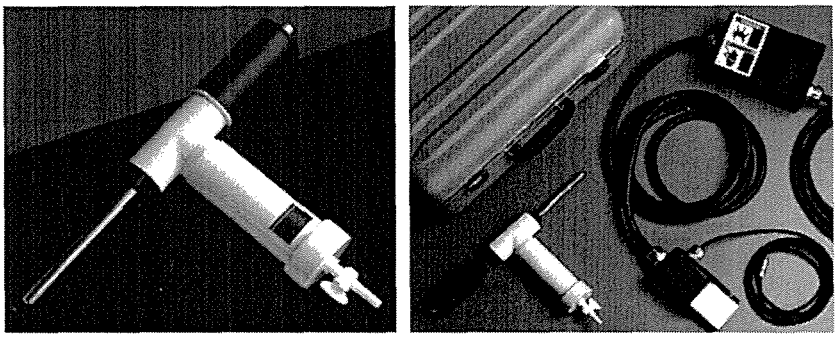


Figure 35 Cook Tissue Morcellator.

The device is operated as follows - (Cook Morcellator - User Manual 1992)

Assembly:

- Remove the disposable morcellator body from the sterile packaging.
- Attach the reusable, non - sterile motor to the morcellator body (Figure 36).
- Attach the non-sterile motor cord to the motor.
- Pull the sterility sleeve over the motor and cord.
- Attach the vacuum tube to the vacuum control on the morcellator, and attach the other end of the tube to the high suction inlet on the hospital wall (500 - 720 mm Hg).
- Plug in the power cord and position the foot pedal appropriately.

Operation:

- The tissue to be removed is placed inside an entrapment sac.
- The neck of the entrapment sac is exteriorised out on of the trocar incisions.
- The morcellator is inserted into the neck of the bag, and placed directly upon the tissue to be morcellated.
- The assisting surgeon provides upward force on the bag (Figure 36a).

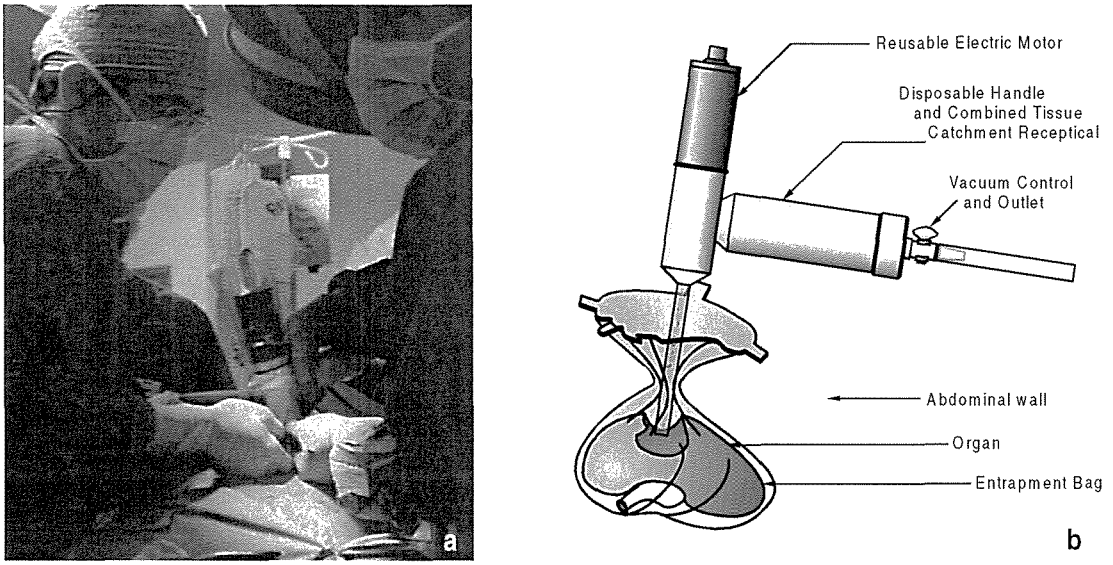


Figure 36 Using the Cook Tissue Morcellator.

- The vacuum control on the morcellator body is opened.
- The foot pedal is depressed activating the morcellating blade.
- The foot pedal and vacuum control can be turned on and off at the surgeons discretion.
- The metal cannula attached to the front of the morcellator is advanced directly into the tissue being morcellated.
- Optimum morcellation is achieved by using methodical strokes to forcibly drive the sheathed rotary scalpel into tissue.
- Once all tissue has been morcellated and sucked into the collection chamber, the vacuum and power are turned off.
- The empty entrapment sac is removed out through the incision.
- The base of the collection chamber is removed and the specimen sent to pathology.

Disassembly:

- Wall suction is turned off.
- Power unplugged from the wall.
- The sterility sleeve is removed and the electrical cord is disconnected from the motor.
- The motor is removed from the morcellator body.
- The morcellator body is disposed of.

Discussion:

As outlined above, the numerous assembly steps required to prepare the device for use in a sterile environment are poorly controlled and thus present the risk of contaminating the sterile field. When attaching the non-sterile motor to the sterile handle, the scout nurse may slip or fumble and bring the motor into contact with the sterile morcellator body. Similarly, when attaching power cords, the sterile field may be contaminated by poor management of the leads (Riemann, 1993). The suction tube has no point to define where the sterile field begins and ends. Such undefined junction points can produce contamination of the sterile field.

The morcellator is restricted in the tissues which it can successfully extract (Kanehira, et.al., 1994). Specimens containing staples and clips risk damaging the morcellation blades. This is a significant problem as many major dissections are performed using automatic stapling and cutting devices.

The suction control tap requires a turning on and turning off motion to control. Such a tap lacks the ability to be instantly switched off should a problem arise. In this situation, very high levels of suction are being used (almost 1 atmosphere), and a trigger with automatic switch off may have been a safer solution.

The correct function of the morcellation process relies on the specimen being sucked into the blades. The assisting physician must pull up vigorously and continuously on the entrapment bag to prevent the formation of small folds which may be potentially sucked into the rotating scalpel blades (Urban, et.al., 1993). The morcellation process takes several minutes, over which time the assisting physician's arm becomes fatigued from maintaining continuous, strong upward force. Due to this fatigue the assistant may inadvertently relax

their grip, and cause a fold to form in the entrapment sac which may be sucked into the morcellating blades.

The resultant specimen produced by the Cook morcellator has produced concern amongst the medical community and pathologists (The specimen produced is an almost liquefied puree of tissue). The samples of tissue are typically 1.0mm x 0.5mm x 0.3mm (Lobe, et.al., 1994). These samples appear to retain microscopic architecture, however gross relationships are totally destroyed and tumour margins are no longer definable. (Lobe, et.al., 1994). To accurately stage tumours the surgeon is required to take selective samples from the tissue while in the entrapment sac. These samples can then be placed in separate jars and labelled accordingly to be sent to pathology. Although this solves the problem of ill defined tumour margins it creates two extra problems: To obtain the tissue samples the surgeon will need to use scissors within the entrapment bag which may cut or perforate the bag, the second problem is the increased operative time required to gather the samples and label them to be sent to pathology.

The cost of the Cook device is $2964.50 for the reusable motor, foot pedal and power cord, and $200.20 for each disposable package containing a morcellator with blades and tissue collection chamber, vacuum control and collection chamber filter, and 200cm plastic sterility sleeve.

The advantage of the Cook morcellator is that no additional trauma is caused to the patient, and thus the benefits of endoscopy are in no way forfeited by the extraction process.

Steiner Electrical Cutting Device

The principal function of this instrument is to cut the tissue into cylinder-shaped pieces with a rotating knife that is driven by an electric motor (Steiner, et.al., 1993). The device has only been described as a prototype and is not available as a commercial product (Figure 37).

Preparation and assembly details have not been published. On the basis that the Steiner cutter is a foot operated, electrically powered device, it is assumed that the set up procedure would not differ very much from the Cook morcellator.

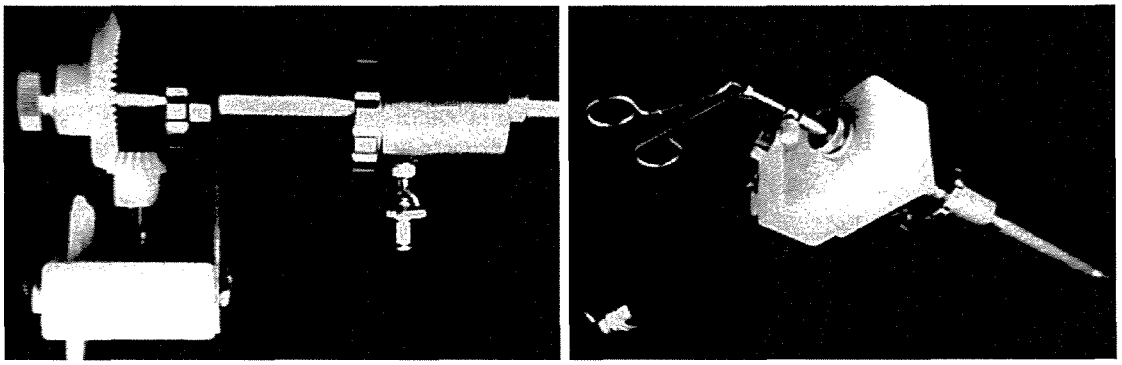


Figure 37 The Steiner Electrical Cutting Device.

(Steiner, et.al., 1993)

Operation:

- The mobilised tissue is placed in an open area for removal.
- The electrical motor is attached to the gear box.
- The cutting cylinder with attached gearbox, motor, and integral forceps are inserted down a cannula.
- The tissue to be removed is grasped and pulled up against the blade (Figure 38).
- The foot pedal is depressed and a cylindrical tissue volume is cut out of the main specimen.

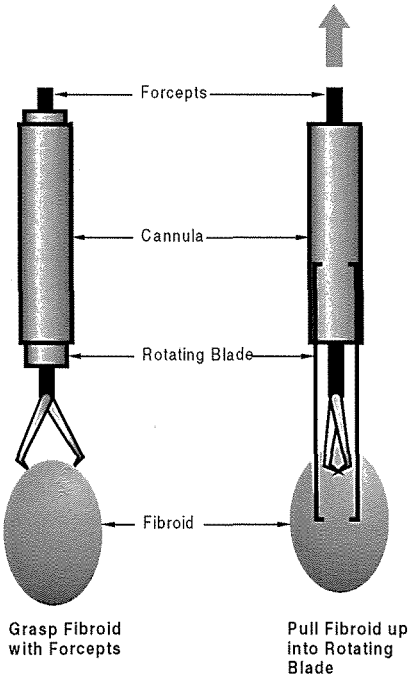


Figure 38 Workings of the Steiner Cutter.

(Steiner, et.al., 1993)

- The main specimen drops back to the visceral bed, and the dissected cylinder is immediately removed from the patient using the forceps.
- The forceps are reinserted and the main specimen is grasped again.
- The process is continued until the entire specimen is removed from the patient.
- An encapsulation sac is not used with the procedure.

Discussion:

The Steiner device is not intended to be used with an encapsulation sac. This results in substantial spreading of the diseased tissue over the operative site. This does not present a problem when removing fibroids or some ovaries, however it totally prevents the removal of tissue which may cause disease or cancer spreading throughout the abdominal or thoracic cavity. Contamination of the incision sites has been reported in situations where diseased tissue has come into contact with the wound (Cagir, et.al., 1994).

The complex mechanics of this device suggest a similar degree of complexity involved with preparation and assembly as to the Cook Morcellator. The numerous components and cords demand careful attention to prevent the contamination of the sterile field.

Patient safety is compromised by the use of this device. The exposed blade can be inadvertently advanced into healthy tissues within the patient. A lack of safety features allows possibly accidental activation of the foot pedal. Should this occur while the main specimen mass is being grasped from the visceral bed, then the rotating blade could cut into the bodily structures around the pick up site.

The exposed blade also presents a risk to the surgeon and the nursing staff. The sharp blade could easily break the sterile barrier provided by surgical gloves. The sharp edges also create handling problems for the cleaning and handling staff.

Although the cost of the device is not available, the elaborate mechanics and electrical motor would suggest a substantial investment is required to purchase such a device.

Some features of the Steiner cutting implement are good. The quality of the specimen supplied to pathology is very high. The cylindrical samples are

cleanly cut, and can be taken from selective sections of the specimen. The circular blade can slice through a variety of tissues and will automatically go around any clips or staples (Steiner, et.al., 1993).

The purpose of any prototype is to provoke constructive criticism, and provide a testing opportunity for an invention. It is expected that the inventors of the Steiner cutter have listened to much critical evaluation of their product, and hopefully, have pursued to substantially improve their device before proceeding with development for mass production.

Cuschieri Tissue Slicer

The Cuschieri tissue slicer is another device available as a prototype only (Figure 39). The main reason for including it is because Doctor Cuschieri is one of the world leading surgeons in endoscopy. He is responsible for founding several endoscopic surgical procedures, and for providing a leading example in the field of surgical advancement, instrument research, and development.

The device uses a semi protected blade to slice up the selected specimen within an encapsulation sac, after which the bag end is exteriorised and the slices are removed manually.

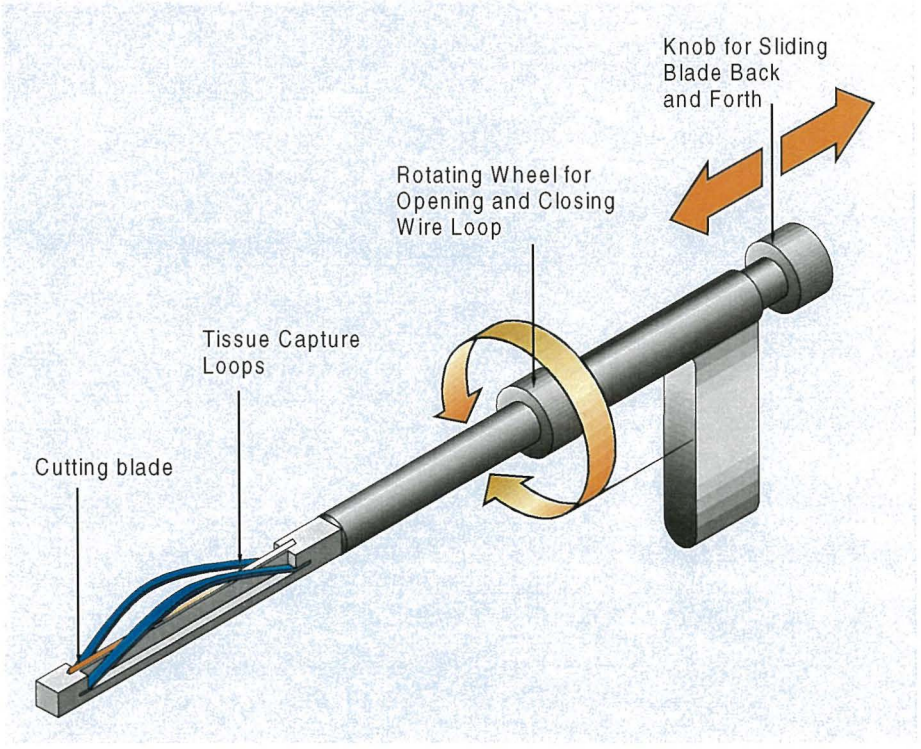


Figure 39 The Cuschieri Tissue Slicer.

The assembly of the slicing device has not been described in the published material, however the instrument is an entirely metallic device (except the encapsulation sac) designed for re-sterilisation and multiple operations.

Operation (Cuschieri, Frank, 1994):

- The special entrapment sac made with a small and a large opening is introduced into the peritoneal cavity.
- The small opening is removed out one of the cannula, and the large opening is positioned for organ entrapment.
- The organ is entrapped and the large bag opening is exteriorised out another cannula.
- The endoscope is inserted down the small opening into the bag, and the slicer is inserted down the large opening (Figure 40).
- The wire loop is manoeuvred around the organ and closed using the rotating wheel.
- Sliding the rear knob back and forth moves the cutting blade to and fro, and slices through the organ.

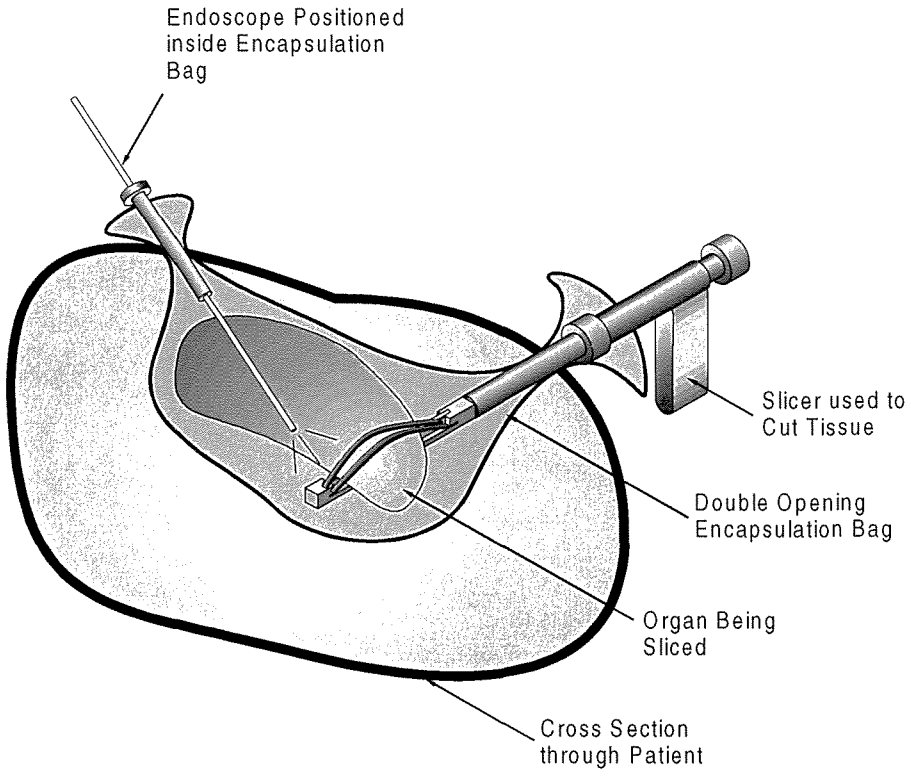


Figure 40 Cuschieri Tissue Slicer - Operation.

- The process is repeated until the organ is sliced into pieces of suitable size for removal out the large bag opening.
- Using forceps the organ slices are removed and sent to pathology.
- The small opening in the bag is ligated, and the entire bag is removed.

Discussion:

The Cuschieri device represents a technologically simple solution. It is capable of slicing a wide variety of tissue variants, and provides excellent samples for pathological examination. The cost of the proposed design would be substantial, but not near as expensive as a motorised device. The only criticisms of the device concern its safety, and ease of use.

The slicing blade of the device is moved back and forth through the clamped tissue. This all takes place within the encapsulation sac. There is a risk that the exposed slicing blade could penetrate through the encapsulation sac and cause diseased cells to be spread throughout the operative site. A more serious situation may arise if the blade were to cut through the bag and into external healthy tissue or vascular structures.

To successfully operate the Cuschieri slicer the surgeon is faced with the difficult task of simultaneously manipulating, organ, bag, and slicer. The process of consecutively securing the tissue slicer around the entrapped organ requires considerable surgical skill. For large specimens such as inflamed spleens or kidneys, the process of slicing could take well over fifteen minutes.

As stated with the Steiner device, it is important to remember that the Cuschieri slicer is only a prototype. With further development, and addressing the safety, and usability issues, the Cuschieri slicer has the potential to provide a useful solution to the problem of organ extraction.

"Bergetrokar" Large Trocar

The Bergetrokar is a 20mm cannula with trumpet valve and cone tip that can be spread to form an open conical shape (Figure 41). The design has primarily developed for application in laparoscopic cholecystectomy to remove gall bladders containing a large quantity of gall stones. The application of the "Bergetrokar" has been widened to include extraction of other organs or large tissue specimens.

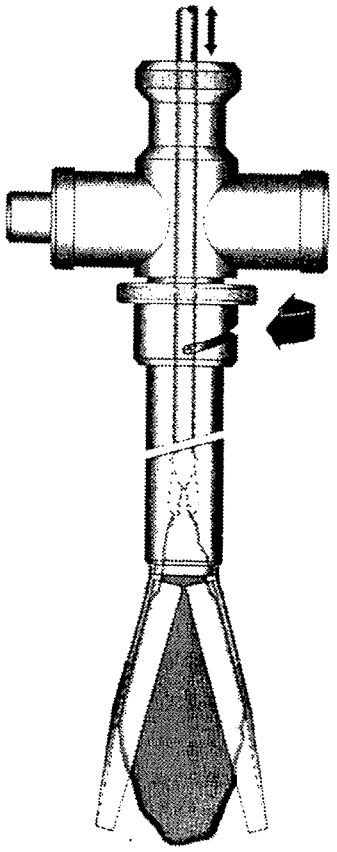


Figure 41 The "Bergetrokar".

(Hoferlin, and Hohle, 1993)

The design is published as a prototype design, - not an article of mass production (Hoferlin, and Hohle, 1993). From the illustration it can be seen that that the Bergetrokar is well developed and could be considered to be a good representation of the intended final product.

The device is constructed of stainless steel and is totally suitable for numerous sterilisation cycles. It would be logical to assume that the product would be handled in a similar manner to present reusable endoscopic cannula.

Operation (Hoferlin, and Hohle, 1993):

- The cannula is inserted into the patient through one of the existing trocar incisions. (Section 3.1.2, p86).
- Rotating the lower knurled ring, allows the half shells to spring open.
- Forceps are inserted down the trocar to grasp the organ for extraction.
- The specimen is pulled up into the half shells and into the cannula.

- In some instances the bile of the gall bladder has to be aspirated before the organ will fit between the half shells.
- The entire cannula and contained specimens are withdrawn.

Discussion:

The "Bergetrokar" works by spreading the force of withdrawal over a large surface area. The spreading of the load prevents the organ from ballooning and jamming around the extraction site.

The "Bergetrokar" is limited in its application. The device cannot be used to extract large organs such as kidneys or spleens, and the large cannula diameter prevents it from being used in thoracoscopic surgery. The implement is very suited to removing small fibroids, and appendices.

The biggest drawback associated with this unique cannula is that it causes additional trauma to the patient, in the form of an enlarged incision, and compromises the endoscopic approach to surgery. (Section 3.1.2, p86).

The positive aspects of the design is its ease of use. The simple design concept is easily identifiable and improves the marketability of the product. The “Bergetrokar” is physically similar in size, complexity and materials to a reusable cannula, therefore the cost of this instrument is anticipated to be relatively equivalent to the cost of a reusable trocar / cannula.

Blunt Dissection Using Scissors and Surgeons Fingers

Although not the most elegant or effective method of extraction, manual morcellation of an encapsulated specimen is commonly performed. As the name suggests, the surgeon uses no specific instrument to perform the technique. Scissors, lavage implements, blunt probes, and the physicians fingers are all used for this method of extraction used.

Operation (Koyle, et.al., 1993):

- The organ is encapsulated within the pouch.
- The neck of the bag is exteriorised out on of the trocar incisions.
- The surgeon inserts an instrument into the bag and manually breaks apart the specimen.
- The surgeon will often enlarge the incision to 20mm.
- Scissors are sometimes used to dissect the encapsulated specimen.

- As the pieces are formed they are exteriorised from the bag, and placed into a kidney dish.
- Once all the tissue is removed the bag is withdrawn.

Discussion:

The only positive aspect of this extraction technique is that aside from the encapsulation bag, no additional equipment has to be purchased or prepared for theatre.

An extended application of force and physical determination is required by the surgeon to totally dissect a specimen and remove it. The physical exertion required makes this technique totally unsuitable for use on fibrous or tough tissues. The high level of force creates a safety problem, as the physician may accidentally puncture or even rupture the encapsulation bag. Blindly using scissors within a bag could easily cut a hole in the pouch and cause diseased cells to spread over the operative cavity.

The vigorous actions of the surgeon bruise the wound site and cause additional trauma to the patient. The enlargement of the trocar incision is a compromise of the endoscopic approach to surgical treatment.

The pathological condition of the retrieved specimen is dependant on the patience of the physician. Typically the tissue is in large pieces, but has been ripped and distorted by the extraction process. Vascular structures are ripped from the softer visceral tissue and thus gross pathology is lost or severely affected.

3.2.3 The Analysis

Each instrument is evaluated against a list of design criteria. The criteria are based on the performance objectives used for the analysis of organ extraction techniques in Section 3.1.2, p86. The evaluation criteria have been grouped under the headings of:

- Function
- Safety
- User Needs
- Maintenance / Cleaning
- Marketing.

Function

Functional characteristics assessed include:

- Ability to remove a variety of tissues ranging from fibrous tumours to soft cystic specimens.
- The time required to assemble, use, dissemble and clean the device.
- The ability of the instrument to remove tissue containing metallic clips and staples.
- The additional trauma caused to the patient by the extraction process which compromises the endoscopic approach to surgery.
- How well a diseased sample is isolated from the operative site.
- The quality of the sample presented for pathological examination.
- The affect on pneumoperitoneum.

Safety

Safety aspects investigated:

- The safety of the patient during the proper intended use of the instrument.
- The safety of the surgeon and assisting staff during the proper anticipated operation of the device.
- Foreseeable injury to patient from incorrect use or instrument malfunction.
- Foreseeable injury to physician and assistants from incorrect use or implement failure.

User Needs

User needs evaluated are:

- To what extent does the surgeon remain in control of the extraction process throughout the procedure.
- The complexity, and task logistics required to correctly use the device.
- Ergonomic considerations, muscular comfort, and appropriate body posture.
- Complexity of the sterile handling procedures and the possibility of the sterile field being contaminated.

Maintenance / Cleaning

The maintenance and cleaning issues examined :

- The ease at which the instrument can be cleaned and re-sterilised.
- The level of training required to properly clean and process the device following its use.
- The safety of the nursing staff during the cleaning and maintenance process.

Marketing

Assessment of the qualities perceived as affecting the marketability of the product:

- The additional instrument cost incurred.
- How suitable the device is for sale in each of the endoscopy markets including, laparoscopy, thoracoscopy, and paediatrics.

Matrix Analysis of Instruments used for Endoscopic Tissue Extraction

The following matrix (Figure 42) was compiled using an identical process to the matrix described at Figure 34, p93. In addition to the process described at Figure 34, p93 an instrument subtotal score is noted at the end of each of the design criteria categories (Function, Safety, Maintenance / Cleaning, and Marketing). The subtotal score is weighted, along with the maximum possible score for that subsection.

Weighting	Design Criteria	Tissue Morcellation Implement				
		Cook Morcellator	Steiner Electrical Cutter	Cuschieri	Bergetokar	Scissor and Blunt Dissection
10	**Function**					
	Remove a variety of tissues	■■■■□	■□□□□	■■■■■	■□□□□	■■■■■
	Time to conduct process	■■□□□	■■■□□	■■□□□	■■■■□	■□□□□
	Remove tissue containing staples & clips	■■■■□	■■■■□	■■■□□	■■■■■	■■■□□
	Compromise endoscopic approach	■■■■■	■■■■■	■■■■■	■■■□□	■■■■■
	Contain Disease	■■■■■	■□□□□	■■■■■	■■□□□	■■■□□
	Pathological Requirements	■■□□□	■■■■□	■■■■□	■■■■■	■■■■□
	Maintain Pneumoperitoneum	■■■■■	■■■□□	■■■■■	■■■■■	■■■■■
	Total out of / Theoretical Maximum of 350	240	210	290	250	260
10	**Safety**					
	Safety of patient during use	■■□□□	■□□□□	■■□□□	■■■■■	■□□□□
	Safety of surgeon during use	■■■■□	■□□□□	■■■■□	■■■■■	■□□□□
	Possible patient injury from incorrect use	■□□□□	■□□□□	■□□□□	■■■■□	■□□□□
	Possible surgeon injury from incorrect use	■□□□□	■□□□□	■□□□□	■■■■■	■□□□□
	Total out of / Theoetical Maximum of 200	80	40	80	190	40
8	**User Needs**					
	Surgeon in constant control	■■■□□	■■■□□	■■■□□	■■■■□	■□□□□
	Easy and logical to use	■■□□□	■■■■□	■■■□□	■■■■■	■■□□□
	Comfortable user posture and grip	■■□□□	■■■□□	■■■□□	■■■■■	■□□□□
	Simple and safe sterile handling	■■□□□	■■□□□	■■■■□	■■■■■	■■■■■
	Tota out of / Theoretical Maximum of 160	72	72	80	152	72
6	**Maintenance / Cleaning**					
	Easy of maintenance / cleaning	■■■■□	■■■■□	■■■□□	■■■■□	■■■■■
	Training required for cleaning/maintenance	■■■□□	■■■□□	■■■□□	■■■■□	■■■■■
	Safety of nurse during cleaning	■■■■■	■□□□□	■□□□□	■■■■□	■■■■■
	Total out of / Theoretical Maximum of 90	72	48	42	72	90
5	**Marketing**					
	Additional instrument cost	■□□□□	■□□□□	■■■■□	■■■■■	■■■■■
	Application to thorac., Lap., & Paediatrics	■■■■■	■■■■■	■■■□□	■□□□□	■■■■■
	Total out of / Theoretical Maximum of 50	30	30	35	30	50
	Total Score out of 850	**494**	**400**	**527**	**694**	**512**

Legend: ■ = 1, □ = 0, ■■□□□ = 2 out of 5

Figure 42 Matrix Analysis of Instruments used for Endoscopic Tissue Extraction.

3.2.4 Interpretation of Results

All scores and ratings contained in the following section refer to the results established through the matrix analysis (Figure 42, p111).

Analysis shows the "Bergetrokar" as the highest scoring overall product (scoring a total of 694 out of a possible 850). This is directly related to the level of development exhibited by the product. It should also be noted that the product only scores poorly in those areas (remove tissue variety - 1 out of 5, contain disease - 2 out of 5, and application to laparoscopic, thoracoscopic, and paediatrics - 1 out of 5,) which it was not originally designed for, except for compromise of the endoscopic approach. These inadequate aspects of the "Bergetrokar" are however, some of the absolute key objectives required by a tissue extractor, therefore the design does not provide an all over satisfactory solution.

The "Bergetrokar" is the only design which scores consistently well in the safety and user needs category. This can also be attributed to its design and engineering details.

Functionally the most promising device is the Cuschieri slicer (scoring 290 out of a possible 350 for the Function category of the Design Criteria).

All of the morcellation instruments achieve poor scores in the safety and user need sections (80, 40, 80, and 40, out of a possible 200). This is caused by their use of sharp blades, large forces, and the complex sequence of steps required for use the devices. The "Bergetrokar" and technique of "blunt dissection using scissors or surgeons fingers" score very well in the sections of maintenance / cleaning (72 and 90 out a possible 90), and marketing (30 and 50 out of a possible 50), because they use simple solutions at a low cost.

3.2.5 Summary

Three key conclusions are drawn from this analysis. When designing an implement for tissue and organ extraction in endoscopy it is important to follow these three objectives:

Design for performance. Any proposed product needs to function efficiently, reliably and as intended. Satisfy all design criteria through design, attention to detail, and quality engineering.

Design for safety. The safety of any medical instrument is critical. Avoid producing a situation which has the potential to harm patients and/or practitioners.

Design for simplicity. Simple, effective, design solutions have definite positive aspects, particularly in terms of usability, cost, and marketability.

3.3 Tissue Retrieval Bags for Endoscopy

Some of the extraction devices and techniques described earlier in this chapter are used in conjunction with a tissue retrieval bag. The bag provides a means of isolating diseased tissue from healthy structures. The strength of a bag also prevents brittle structures from breaking apart or bursting during the removal process.

All bags are used in a sequence of four steps:

- 1. Insertion into the patient.
- 2. Opening up inside the operational cavity.
- 3. Manoeuvring the tissue inside the bag.
- 4. Exteriorisation of the bag.

The design of the bag substantially affects how easily and quickly a surgeon can perform these four steps. This section presents a small selection of bag designs and provides comments on the characteristics of each product. An in depth comparative analysis of the different bags is not attempted as there is limited published material offering discussion on individual bags.

3.3.1 Description and Evaluation of Encapsulation Bags for Endoscopy

The bags selected for inclusion all have individual design features aiming to solve similar problems. In addition the variety of material used to construct the various bags is described.

The bags studied include:

- Tissue Retrieval System by Espiner Medical Products.
- EndoSac
- LapSac by Cook Urological
- EndoPouch by Ethicon Endo-Surgery, a Johnson and Johnson Company.
- EndoCatch by AutoSuture, a division of US Surgical Corporation.

Tissue Retrieval System by Espiner Medical Products.

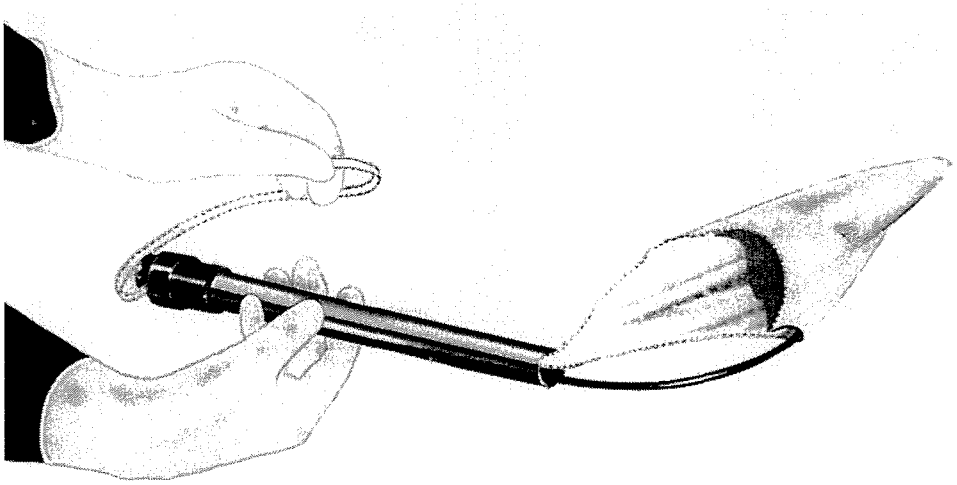


Figure 43 The Espiner Tissue Retrieval System.

(Espiner, 1993)

The action of deploying the Espiner bag appears smooth and simple (Figure 43). The idea of injecting and opening up a bag in one constant movement is simple and neat. Entrapment of the organ becomes difficult as there is no hard edge around the bag. Applying tension to the bag with the plunger alleviates some of the problem. The long tab extension on the bag also presents itself as a good feature as it provides a direct link between the surgeon and the sac. This avoids the loss of tactile feedback associated with using forceps (Espiner, 1993).

EndoSac

Some the first extraction bags used were condoms. The EndoSac is essentially a specially modified condom for tissue extraction (Figure 44). The manufacturers claim EndoSac is easy to insert and that no introducer is required. The possibility of tearing / puncturing a rubbery bag down through a surgical port is questioned. The polyurethane shape opens up automatically upon insertion. Capturing the organ is made simple by the rigid lip around the bag. The instrument gripping tabs allow the insertion, scooping with, and retrieval of the bag, without the need to alter grasping instrument position (EndoSac, 1992).

Figure 44 The EndoSac.

(EndoSac, Advertisement, 1992)

LapSac by Cook Urological

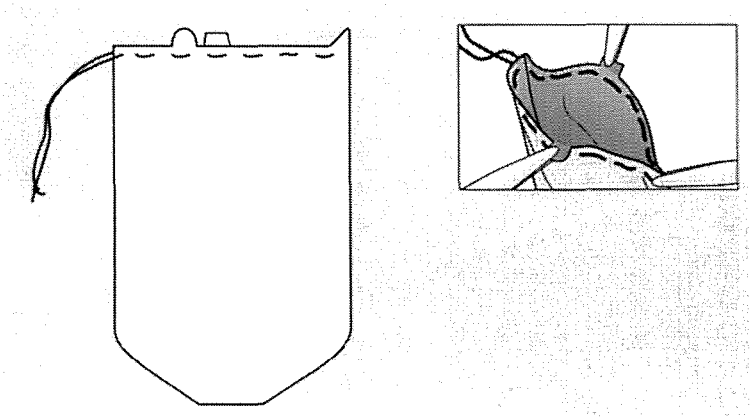


Figure 45 The Cook Urological LapSac.

(Cook Urological, 1992)

The LapSac is a fabric bag constructed of a folded nylon material, heat sealed along the edges to form a pouch (Figure 45). A separate introducer is sold to make insertion easy. This bag is difficult to insert (Figure 29, p87) as the material tends to slide and bunch up at the mouth of the trocar. The LapSac is manufactured and distributed as a flat object, this makes opening difficult as the natural position of the bag is closed. Three forceps are required

to hold the bag open while the organ is manoeuvred inside (Nathansen, 1994). There is no lip on the soft edged bag to help improve encapsulation. Once captured the drawstring prevents the contents from falling out. The grasping forceps position is changed from the side of the bag to the drawstring for removal, an added step in the overall extraction process.

EndoPouch by Ethicon Endo-Surgery, (Johnson & Johnson Company)

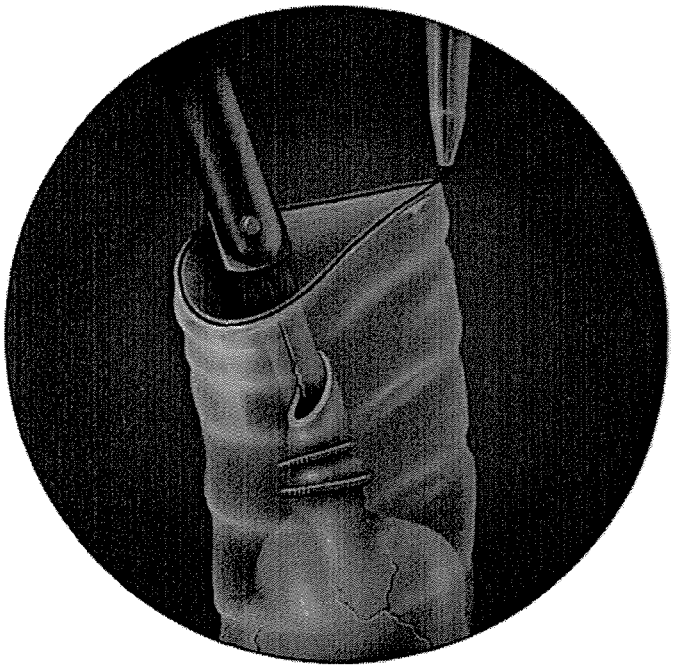


Figure 46 The Ethicon EndoPouch.

(Johnson & Johnson, 1992)

EndoPouch (Figure 46) is a plastic bag. EndoPouch is inserted by rolling up the bag and pushing it down the introducer or cannula with the attached rod. Once inside the patient, the bag has to be opened with forceps. The bag does not have a rigid edge but it does have a doubled over wall around the mouth of the sac. Multiple forceps are still required to successfully stabilise the bag for tissue encapsulation. Extraction is made easy by the attached rod. Pulling back on the rod closes the top of the bag and removes it from the patient (Johnson & Johnson, 1992).

EndoCatch by AutoSuture, a division of US Surgical Corporation.

The operation of EndoCatch is demonstrated by Figure 47. The design is simple to insert, and provides an excellent rigid edge for tissue encapsulation. The built in draw string helps prevent accidental spillage of captured

specimens. The design is highly effective and very successful (AutoSuture, 1994). The only disadvantageous aspect to the design is the increased expense incurred by the more complex nature of the product.

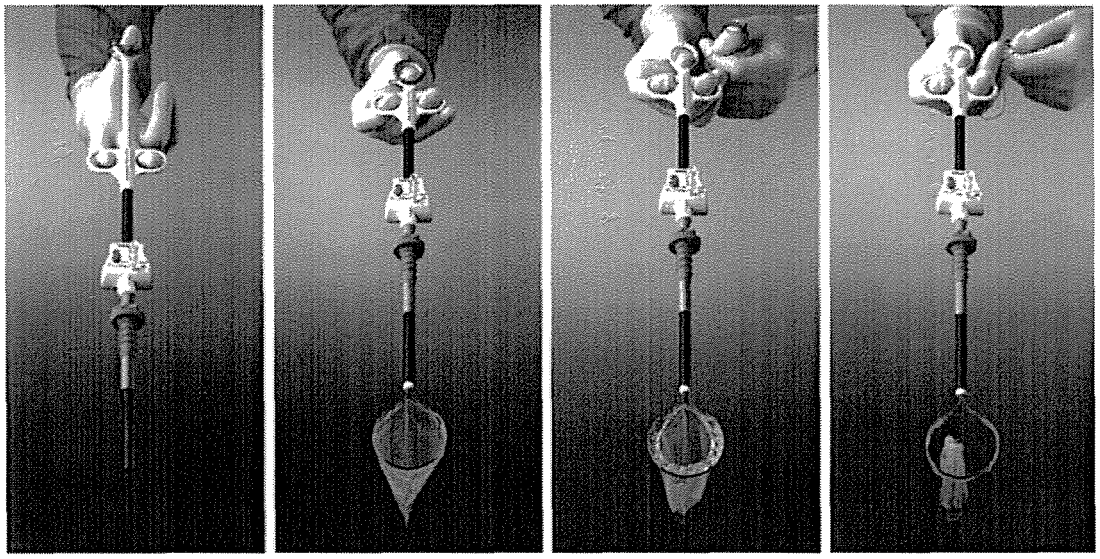


Figure 47 Extract by AutoSuture.

(AutoSuture, 1994)

3.3.2 Summary - Implications for a Bag Design

It is desirable that bags for tissue encapsulation be distributed and supplied at the sterile field ready for immediate insertion. Using one continuous action the surgeon should be able to insert and open up the bag for tissue encapsulation. Features should be incorporated into the design to aid manipulation of the organ into the bag. A direct connection between the surgeon and the bag is desirable, particularly when firm force is being exerted on the bag during exteriorisation. The bag design must be simple and economical as the product is disposable. Excessively elaborate designs will be rejected in favour of cheaper simpler products such as the EndoPouch.

3.4 Summary

The analyses conducted in Chapter 3 outlines the current status of tissue extraction in endoscopy. The analysis illustrated the advantages and disadvantages of the organ extraction techniques and instruments currently being employed by surgeons.

The conclusions established in: Section 3.1.5, p94, Section 3.2.5, p112, and Section 3.3.2, are used in conjunction with the research established in Chapter 2, to generate the Design Criteria checklist for an endoscopic tissue and organ extraction device (Chapter 4).

CHAPTER 4

Design Criteria

"The soul that has no established aim loses itself." (Montaigne 1533 - 1592).

Design is used to solve complex problems which have multiple interrelated and influential factors. A list of design criteria provides a checklist to follow and refer to as the design progresses. As a design develops, so does the checklist. New criteria are added, and irrelevant items are discarded.

This chapter is the list of design criteria relevant to organ and tissue extraction in endoscopy. The list is based upon observations made during both the research stages, and the design stages of the thesis. The list commenced during general research into the field of endoscopic surgery (Chapter 2). Further criteria were added based upon the results of the analysis of organ extraction in endoscopy (Chapter 3). As design work progressed (Chapter 5), the list continued to be updated and revised.

The list has been divided into eight general categories:

- Aim
- Functional Objectives
- Surgeon / User Needs
- Nurse / User Needs
- Marketing Requirements
- Production Criteria
- Packaging Criteria
- Thesis Specific Criteria

4.1 Aim

The aim of this design research project is:

To research and design an internationally marketable product for the extraction of large tissue specimens and organs in endoscopic surgery.

This includes application of the design in thoracoscopic, laparoscopic, and paediatric surgery.

4.2 Functional Objectives

By establishing a list of product criteria and objectives, proposed design solutions can be evaluated against the list. Functional objectives pertain to the actual task which a device must perform. If a design fails to meet any of the functional objectives, then the device cannot satisfactorily perform the intended task, and thus is not an acceptable product.

The functional objectives for a tissue and organ extraction device, are categorised under the following sections:

- Removal of Tissue
- No Additional Incisions or Enlargement of Incisions
- Contain Diseased Tissue
- Pathological Requirements
- Maintain Pneumoperitoneum.

4.2.1 Removal of Tissue

Issues concerning the physical removal of selected tissue:

- The device shall remove selected tissues from within the patient.
- Specimen varieties including: fibrous tissue, soft tissue, tissue containing clips or staples, or structures containing stones, must all be extractable.
- The design shall be suitable for use with malignant or benign tumours.
- The tissue must be removed within a reasonable time frame.
- The design must be able to remove different size specimens ranging from an inflamed appendix to a large spleen.

4.2.2 No Additional Incisions or Enlargement of Incisions

Requirements relating to trauma of the incision sites:

- No additional incisions can be required.
- No enlargement of existing incisions is acceptable.
- The device will operate through a 10mm or smaller, cannula or trocar incision.
- Incision sites should be exposed to minimal additional trauma.

4.2.3 Contain Diseased Tissue

Constraints pertaining to containment of diseased cells:

- Diseased tissue containing neoplastic cells must be totally sealed off from surrounding structures, and incisions following mobilisation of the specimen.
- There can be no risk of spillage into the body cavity during morcellation or extraction.
- Entrapment systems or bags must be resistant to inadvertent abrasion and puncturing.
- The design should not excessively expose the operative staffs to blood and bodily fluids.

4.2.4 Pathological Requirements

Criteria regarding the condition of the final specimens:

- The removed specimen must be in a suitable condition for the necessary pathological examination.
- Morcellated specimens must be as large as is feasible, and remain small enough for extraction out a 10mm trocar incision.
- The vascular structures should remain fixed to the appropriate viscera, and not be ripped out of the organ during morcellation.
- Cuts made to the specimen must be clean, causing minimal structural damage or permanent deformation.
- Scope must be made for the marking and removal of small tissue samples while the organ is isolated, but prior to morcellation.

4.2.5 Maintain Pneumoperitoneum

Objectives for maintaining a sufficient level of insufflation:

- Gas cannot escape from the peritoneal cavity as the surgeon will loose visualisation of the operative environment.
- Insertion of the device must not cause excessive gas loss.

4.3 User Needs of the Surgeon

Producing a product which functions and works well is extremely important. It is equally important to ensure that the product can be operated correctly and easily, without causing the user any undue stress or harm. User needs are constraints aimed at producing smooth interaction between the product and the user.

Once past the production stage, the only two users who interact directly with a tissue and organ extraction device, are the theatre nursing staff, and the surgeon. Issues pertaining to the user needs of the surgeon are divided into the following categories:

- Control Ergonomics
- Perception and Orientation
- Safety
- Semantics
- Training and Instructions.

4.3.1 Control Ergonomics

Ergonomic issues regarding adequate user control:

- The surgeon must always feel totally in control of the instrument.
- The design must be logical and intuitive to use.
- Feedback on the operating status of the device must be maintained at all times.
- The surgeon must always feel confident and comfortable with the device.
- The handling positions of the surgeon must be appropriate for the different tasks encountered while using the device.
- The controls and handles must be comfortable to use and reach in all appropriate positions.
- The design is to be sympathetic to users wearing surgical gloves.
- Physical dimensions must suit the anthropometric measurements of a five percentile female to a ninety-five percentile male user range.
- The instrument must be able to be rotated through 360° without detrimentally affecting handle ergonomics.

4.3.2 Perception and Orientation

Criteria relating to user perception and orientation:

- End points of the instrument must be clearly visible and defined when using and observing the device through an endoscopic display system.
- A variety of different surface finishes should be used to help understanding of the orientation of the device in use.
- Tactile orientation marks or nodes should be utilised on the operating handles of the device where appropriate.

4.3.3 Safety

Safety requirements pertaining to the user, and the patient:

Patient Safety Issues

- Patient safety must never be in jeopardy or compromised.
- Should an instrument malfunction, then safety measures should be in place to control the failures.
- The device should cause no additional trauma to the patient.
- Products designed for single use only (disposable), should incorporate features that break / activate when the product is first used, thereby making it physically impossible to reuse the device a second time.

Surgeon Safety Issues

- The surgeons personal safety should never be placed at risk by the instrument.
- The instrument must have no sharp corners or other features that might break through the surgeons sterile gloves.
- The design must be safe to use on patients suffering from contagious diseases such as Hepatitis or Acquired Immunity Deficiency Syndrome.

4.3.4 Semantics

Objectives for the product semantics to achieve:

- The surgeon must feel comfortable with the device and confident about using it in surgery.

- The semantics of the design should follow the correct actions and use of the product.
- The semantics must reinforce the disposable or reusable characteristics of the design.
- Highly polished and reflective surfaces should not be used on sections of the instrument which enter the patient or operative field.
- Where possible semi-radio translucent materials should be used to prevent the instrument obscuring intra-operative X-rays or angiograms.

4.3.5 Training and Instruction

Needs concerning training and instructing new users:

- The design must be simple to use and operate, to facilitate easy learning.
- The design should encourage a rapid, novice to expert user transition.
- The design must be feasible for use in training labs.
- A brief set of instructions must be enclosed in all disposable product packages.
- A laminated set of brief instruction should be supplied with all reusable products.

4.4 User Needs of the Nurse

There are two general categories for theatre nursing staff, sterile nurses and scout nurses. "Sterile nurses", are scrubbed and gloved sterile, thus being suitable for handling of sterile implements and working within the sterile field. "Scout nurses" (the second category of nurses) are non-sterile, and are responsible for the non-sterile duties in an operative theatre (e.g. retrieving equipment from the theatre store room).

A tissue and organ extraction device interacts with the theatre nursing staff during delivery and opening of the sterile package, and also during the collection of the contaminated product. Usability criteria particularly relevant to the nursing staff are listed under the following categories:

- Usability
- Cleaning, Maintenance, and Sterilisation
- Instructions
- Identification.

4.4.1 Usability

Usability issues relating to the nurse user:

- Surfaces must be provided on the device for the secure passing between surgeon and nurse.
- The safety of the handling nurse should never be compromised.
- The device must be suitable for placement on the standard sterile instrument trays.
- The tasks required to prepare the device for use should be simple and kept to a minimum (Aorn Journal, 1994).

4.4.2 Cleaning, Maintenance, and Sterilisation.

Requirements for the cleaning, maintenance, and sterilisation (Aorn Journal, 1994):

- Cleaning must be simple, requiring minimal dismantling of the apparatus.
- All corners and grooves must be accessible for scrubbing.

- There should be no sharp corners or edges which may penetrate the cleaning nurses' gloves.
- There should be no inaccessible cavities to capture blood or bodily fluids.
- A fatigued or faulty device should be easily identifiable so that it can be repaired or replaced.
- The device must be suitable for cleaning in automated washers and ultrasonic cleaning machines.
- Disposable devices will require no cleaning, maintenance or sterilisation by hospital staff.

4.4.3 Instructions

Requirements for instructional materials:

- All disposable devices must come packaged with instructions detailing the correct use of the device.
- There should be a "quick reference" , pictorial set of instructions, and also a very detailed full explanatory set of notes.
- The instructions should also contain advice for possible problems which may occur while using the device.
- Reusable devices should be supplied with a full set of instructions. A laminated "quick reference guide" should be included with these instructions.
- Reusable device instructions will contain complete requirements for adequate cleaning and sterilisation.

4.4.4 Identification

Issues relating to adequate labelling and identification:

- All reusable items must have space for engraving of an identification number and hospital name.
- All individual components of the product must have labels to identify their relationship as a set group.

4.5 Marketing Requirements

Through research conducted into the field of endoscopic surgery, discussions with directors of research at medical equipment manufacturers, and communication with practising surgeons, the market niche for an endoscopic tissue and organ extractor was identified (Section 1.1-1.3, pp 16-21; Chapter 2; Chapter 3). Information was collected on the instruments used for endoscopic surgery (Section 2.4, p41; Appendix 2, p259; Appendix 3, p260). A survey of currently available instruments in the endoscopic tissue extraction market was conducted (Section 3.2 - 3.3, pp 96-114). These steps were aimed at providing a base understanding into the marketing requirements of an endoscopic surgical instrument. These measures were taken in acknowledgement that a detailed market analysis and business plan has not been conducted and is beyond the scope of this thesis. However from the information collated, a list of basic marketing requirements, common in many commercially successful endoscopic surgical products, was established.

Four specific sets of criteria are identified as being crucial for the adoption of a tissue and organ extraction device into the market place:

- Aesthetic Appeal
- Perceived Quality
- Cost
- Market Diversification.

4.5.1 Aesthetic Appeal

Aesthetic objectives to enhance market appeal:

- The product must look well designed, engineered, and manufactured.
- A distinctive product image must be projected.
- The aesthetics should be derived from the desired semantics and functional requirements of the design.
- The profession of surgery and medicine will be reflected in the overall appearance.
- The styling shall be contemporary, but restrained, thereby emphasising the newness of endoscopy, while reflecting the sympathetic professionalism associated with surgery and medicine.

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4.5.2 Perceived Quality

Criteria to reinforce perceived quality:

- The design shall project a feeling of quality and professionalism appropriate for medical environment.
- All physical operations of the apparatus must be precise, controlled, and smooth.
- All moving controls should have definitive clicks to signify motion start and end points.
- The product finish, e.g.; partition lines, must be of a high quality.
- All product features are to be essential functional requirements.

4.5.3 Cost

Issues regarding the final instrument costing:

- The cost of a disposable device it to be comparable to the cost of a disposable trocar and cannula.
- The cost of a reusable device should be comparable to the cost of a reusable pair of endoscopic forceps.
- The product must present itself as appropriately priced for the manufacturing cost and quality.
- A disposable device should not appear overly engineered, or as an unnecessary excessive consumption of resources.
- Reusable items should incorporate a disposable component to improve product reliability, product usability, and financial return.

4.5.4 Market Diversification.

Objectives to improve market diversification:

- One base product should service, laparoscopic, thoracoscopic, and similar paediatric procedures.
- The device should not be procedure specific, rather as a general tool suitable for a variety of circumstances.
- Possible modularisation of the design should be explored to expand the design to veterinarian application.

4.6 Production Criteria

Large financial outlays are required to develop and launch a product onto the market. Typically a substantial portion of the outlay will be on the production set up and operational expenses. The design phase directly affects production and manufacturing issues. Failure to address production needs can cause unnecessary expense and wastage of resources. It is therefore important to continually consider the production criteria, and manufacturing requirements, throughout the development of a product design (Redford and Cahl, 1994).

The production criteria will be significantly affected by the selected manufacturer. For the purposes of this thesis, only the basic production requirements are outlined. Production criteria are divided into the following categories:

- Design for Assembly
- Sterilisation Requirements
- Material Selection
- Disposal and Environmental Considerations.

4.6.1 Design for Assembly

Design issues concerning ease of production and assembly:

- The number of components should be kept to a minimum, without sacrificing product quality or function.
- The design should require minimal handling during manufacture to reduce bio-burden.
- Individual part design should conform to the appropriate handling requirements for automated or manual assembly. (e.g. parts should not be too small, or too large if using manual assembly).
- Parts should have a distinctive and correct orientation.
- Parts should have as few stable attitudes as possible.
- Parts should not nest or tangle.
- Parts should not be abrasive or have the ability to puncture the protective latex glove worn by the assembly worker.

4.6.2 Sterilisation Requirements

Criteria specifically related to sterile operating conditions:

- The product must operate within a sterile environment.
- When processed by the chosen sterilisation method, all surfaces of the product must be sterilised.
- The product should be designed to be sterilised in its final package.
- Sterilisation technique suitable for mass production.

4.6.3 Material Selection.

Needs and objectives for correct material selection:

- The material must be suitable for high production number processes.
- The materials must be compatible with the chosen sterilisation technique.
- Materials must be durable in transit and shock resistant.
- If the material fails it should bend beyond its point of elasticity rather than shattering and breaking up.
- The appropriate material must be appropriate for reusable components and disposable parts.
- The material must not be excessively expensive.

4.6.4 Disposal and Environmental Considerations.

Environmental issues pertaining to responsible production and disposal:

- The design must be suitable for disposal by incineration.
- Materials selected should not produce toxins during the incineration process.
- Material consumption should be kept to a minimum.
- The use of recycled materials should be explored, particularly in the packaging.

4.7 Packaging Requirements

The focus of this project tended toward a disposable design (Section 5.2.2, p172). For this reason a package for a reusable product has not been considered. The packaging of the disposable device has only been considered to a conceptual level as packaging details are very significantly affected by the established standard packaging techniques employed by any one organisation.

There are several layers to a product package. Figure 48, illustrates the basic layers of packaging used in a medical product (O'Brien, 1990).

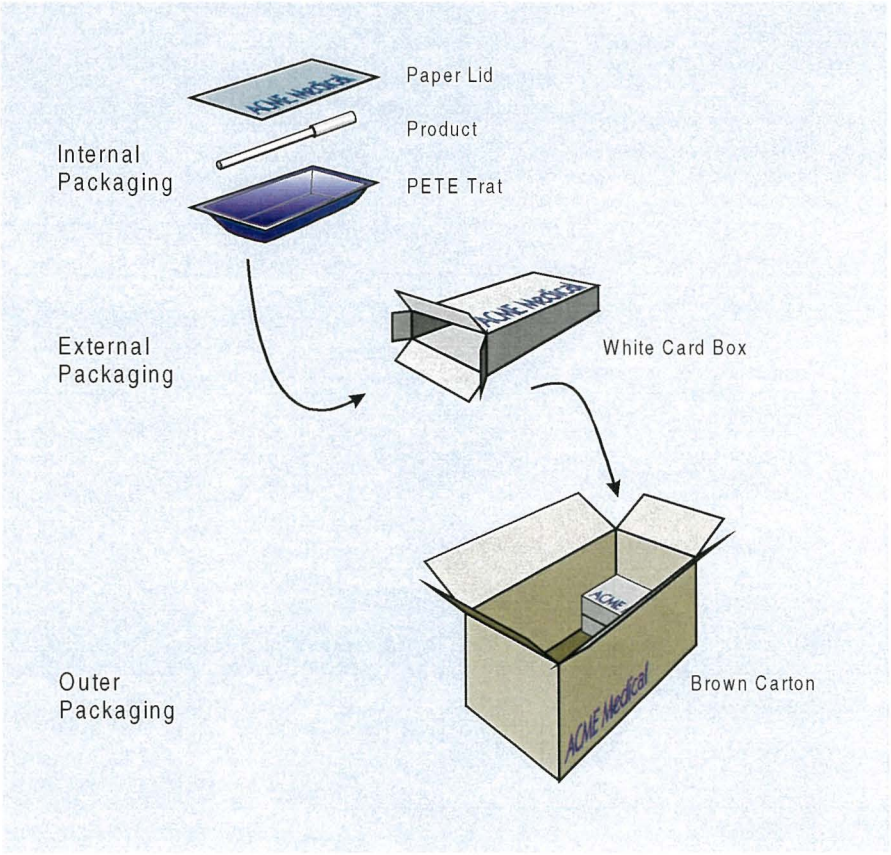


Figure 48 Internal and External Packaging.

- The **Internal Packaging** provides a barrier between the contained sterile instrument and the contamination existent in our general environment.

- The **External Packaging** layer provides a package for the transport of devices in controlled circumstances, e.g. around a hospital theatre

equipment storage room. The external packaging keeps out excessive dust, moisture, and is designed to absorb minor impacts associated with general handling.

- The **Outer Packaging** layer provides protection for transport via general freight including international transport. The box provides protection from excessive dust, moisture, and rough handling.

4.7.1 Aim of the Package Design

The aim of the package design is:

To achieve reliable transfer of the product, from the manufacturer, to the customer.

4.7.2 Functional Considerations

Functional issues of a package design are:

- The package must maintain the sterility of the product.
- All components of the product should be contained in one receptacle.
- Small separate product components should be grouped together in a totally sterile packet that can be placed on the instrument tray within the sterile field.
- The packages dimensions should remain stable throughout the life of the container.

4.7.3 User Requirements

The user requirements to be addressed:

- The external packaging must be easy and simple to open by the scout nurse.
- The nurses must always feel totally in control when retrieving a product from the packaging.
- The sterile cover must be easily peeled open by the scout nurse without contaminating the sterile field.
- Peel off lids should not tear, but come off in one piece.

- The scrub nurse must be able to retrieve the sterile product using one hand, without contaminating the product or themselves.
- Sterile holding trays should have a bottom surface suitable for resting on an instrument tray.
- Handles must be provided on the tray to facilitate correct opening and use.
- Product components should be stored in a logical sequential order.
- Products should be contained securely within the package but should not be excessively difficult to remove.
- Physical dimensions for the handling of the package must be suitable for users within the anthropometric range of 5%ile female to 95%ile male.
- The design must be sympathetic to a user wearing surgical gloves.

4.7.4 Storage / Distribution Needs

Issues pertaining to distribution and storage needs:

- The external package must protect the contents during handling and transit.
- The package should stack efficiently, and tessellate within a box.
- Individual packages must be stable on a shelf or storeroom floor.
- The external package should protect the inner package from excessive dust and moisture during transit.
- The package must protect the product from rough handling, vibration, and impact damage.
- The product must be securely held in place to prevent its movement within the package.
- The device must be contained to prevent it spilling out when the sterile package is opened.

4.7.5 Production Requirements

Production related criteria include:

- The design must be applicable for mass production packaging techniques.
- The material selected must be compatible with the chosen sterilisation method.
- The product pieces must have a specific orientation and placement within the package.

- The package should not be abrasive or capable of puncturing the surgical glove worn by an assembly worker.
- The shape of the package must enable all surfaces to be adequately sterilised.
- The design and materials should respectively not be excessively expensive to produce or utilise.

4.7.6 Package Semantics and Aesthetics

Consideration of package semantic and aesthetic characteristics including:

- A variety of surface finishes should be utilised to improve the semantics of the package, particularly handling points.
- The package must appear well designed, manufactured, and efficient.
- The package should reflect the product image.
- The aesthetics should be derived from the desired functional and semantic requirements of the design.
- The disposable device should not appear excessive and an unnecessary "waste of resources".

4.7.7 Package Graphics

Requirements of graphical information displayed on a package:

- The graphics should be logical to read and easy to understand.
- A consistent graphical style will be utilised on all documentation and pictograms.
- The graphic style followed should be based on the overall product image.

External Packaging

For external packaging the following issues exist:

- Clearly identify the contents of the package, written description and visual diagram.
- Show details of the product manufacturer.
- Describe the sterile nature of the product.

- Space should be provided for details of production numbers and batch numbers.
- All relevant information for dispatching should be contained on the ends of a package so that when boxed, all details can be gathered without unpacking distribution the box.

Internal Packaging

Criteria relating to the internal packaging:

- Contents of the internal packaging should be restated.
- The sterile nature of the packaging should be restated with greater emphasis than on the external packaging.

4.7.8 Disposal

All objects (instruments and packages) introduced into the operating theatre are disposed of in the one receptacle / bag. Therefore environmental issues pertaining to the responsible production and disposal of medical packaging, are identical to those for a surgical device, as discussed in Section 4.6.4 p133.

4.8 Project Specific Criteria

In addition to the above mentioned criteria, there are constraints imposed by the available resources of those performing the development process. The constraints include budget restrictions, time limitations, as well as personal objectives desired by those employed in the project. These criteria have been listed as Project Specific Criteria.

4.8.1 Time

The available time for the project is two years. In this time period, three general tasks are required to be performed:

- Conduct research into the area of organ and tissue extraction.
- Develop and finalise a design solution.
- Document the research, design development , and justification.

4.8.2 Budget and Available Resources

Available funds for the development of the device are limited. Queensland University of Technology has provided $2000 towards the project. Any additional funds required need to be supplied by the author, or by contributions by external bodies.

Resources available for this project include all facilities provided by the Queensland University of Technology. In particular are the laboratories and Computer Aided Design facilities available within the School of Architecture, Interior and Industrial Design.

4.8.3 Overall Project Aims

The overall project aims refer to the wider objectives of the research project. It is anticipated that these wider aims will be achieved by conducting comprehensive research, developing a suitable design, and documenting the work into a thesis.

The wider objectives include:

- The accumulation of a body of knowledge
- The development of a physically operational and working design
- The marketing of the design solution.

Accumulation of a Body of Knowledge

This project must contribute to the body of knowledge available to anyone looking at developing a medical instrument. The documentation will be particularly relevant to designers working in the field of hand held, sterile devices, used in the endoscopic surgical environment.

Development of a Physically Operational Device

A key personal objective of the author is that a working device is built and tested. The design must be more than a theoretical solution, it must actually be proved to perform its intended task. The device should first be tested in a laboratory in a mock up situation. Time and resource permitting, a sterile device may be developed and tested on animals and a patient.

Marketing of the Design

Following the development of a working design, a provisional patent application is to be taken out and the intellectual property associated with the design is to be marketed. Marketing of the intellectual property will achieve three benefits:

- Revenue may be produced to reclaim funds spent on this project and provide finance for future projects.
- The knowledge gained by actually selling a project will act as a stepping stone for the marketing of future projects.
- Contacts within medical companies will be established, for the benefit of both the University and the designer / author.

4.9 Summary

The list of design criteria outlined in Chapter 4, was generated using the research and conclusions established in Chapters 2 and 3. The list documents and categorises, criteria relevant to the design of products, which aim to remove large tissue specimens and organs at endoscopy.

At its inception, the checklist established a starting point from which the design process described in Chapter 5 could commence. The design criteria list (Chapter 4), was continually updated and revised over the entire design research process (Chapter 5).

CHAPTER 5

Design Development and Methodology

"Always design a thing by considering it in its next larger context - a chair in a room, a room in a house, a house in an environment, an environment in a city plan." (Eliel Saarinen 1956).

When conducting a design project it is important to keep a record of the history of the project. This may be in the form of a concept / sketch book or written log. As a project progresses there is an extensive body of ideas and analytical thinking accumulated. The majority of these ideas will be unused, and seem incidental to the project, however when examined as a combined record, distinct thought patterns begin to emerge. By analysing the design process of this project, it is possible to document the design methodology employed.

Presenting the design development and methodology aims to achieve three things: Firstly it provides a case study for those conducting a similar design project; Secondly, the record of notes, drawings and thought processes will provide specialists in design methodology with a body of literature suitable for a detailed case study; Thirdly, the records show key decisions, and demonstrates the quantity and quality of the work conducted to complete the project.

In several places throughout this chapter reference is made to a "user approach". A user approach represents the proposed method for the user (in this case a surgeon) to interact with, and operate the proposed device.

This chapter is comprised of four sections, each corresponding to the four main stages of the project.

- Research: Establish a User Approach
- Invention: Achieve Function
- Definition: Specify User Approach and Product Function
- Solution: Formation of a Marketable Product.

At the end of each section there is discussion on the relative merits and problems associated with that stage of the design process.

The chapter closes with a brief summary.

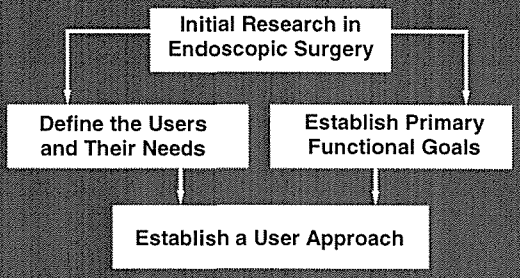
As a summary of the entire design process, a graphical representation of the design methodology model has been established (Figure 49, p145). To improve association of the individual sections with the overall project methodology, parts of the graphical representation are displayed throughout this chapter.

In reference to Figure 49 (The Design Process), the graphical representation is broken into four sections to correspond directly to the four main stages of the design research project. The flow diagram displayed on the left hand side of Figure 49 illustrates the important steps taken during each stage of the research project. Parallel to the flow diagram are corresponding notations, briefly explaining the focus of each step. The design process is discussed in much greater detail throughout Sections 5.1 - 5.4.

This chapter on methodology is presented and discussed as a retrospective study of the design process. The design methods used were based upon the designers knowledge and experience, consultations of appropriate literature, and suggestions received from colleagues.

The Design Process

Stage 1 Research: Establish a User Approach



General reading into the field of Endoscopic Surgery

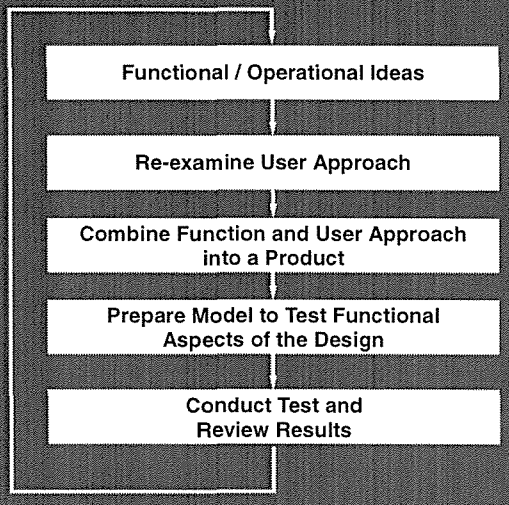
Continued literature review.
Observational studies of operating theatre.
Interview surgeons and nursing staff.
Meet medical company representatives.

Instigation of Design Process.
Ideas generated regarding preferred methods for a user to operate a tissue and organ extraction device.

Stage 2 Invention: Achieve Function

The cyclic pattern below was repeated four times, corresponding to the four design phases of the stage:

Functional Development Phases 1-4



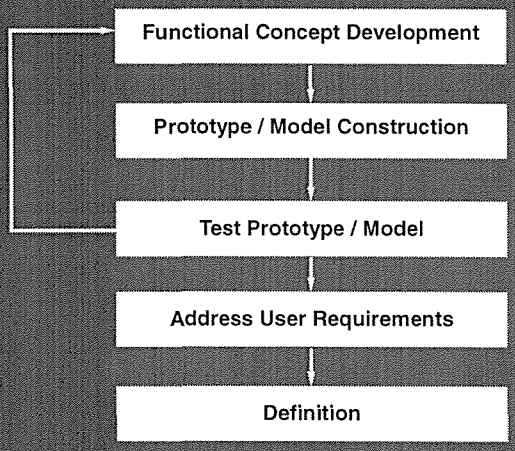
Emphasis shifted between:
Phase 1 - Initial Overall Product Ideas
Phase 2 - Explore Methods of moving tissue through 10mm incision.
Phase 3 - Focus on ways of slicing up tissue.
Phase 4 - Explore bag sealing. Combine Seal, Slice, Extract, into one solution.

Brainstorming and idea generation into methods of extracting an organ which conform to the user approach.

The User Approach is re-examined in combination with the functional concept.

Using drawing and Sketches, The User Approach and Functional Idea are combine into a Product Concept.

Stage 3 Definition: Specify User Approach & Product Function



Refinement of the functional ideas established during Stage 2 - Invention.

Models and prototypes were constructed to test the design.

The tests were conducted and the design further refined.

Updating and refinement of the User Approach, Following the emergence of distinctive functional concept.

Final Definition of the specific functional characteristics of the design. Final User Approach for the design to adhere to specified.

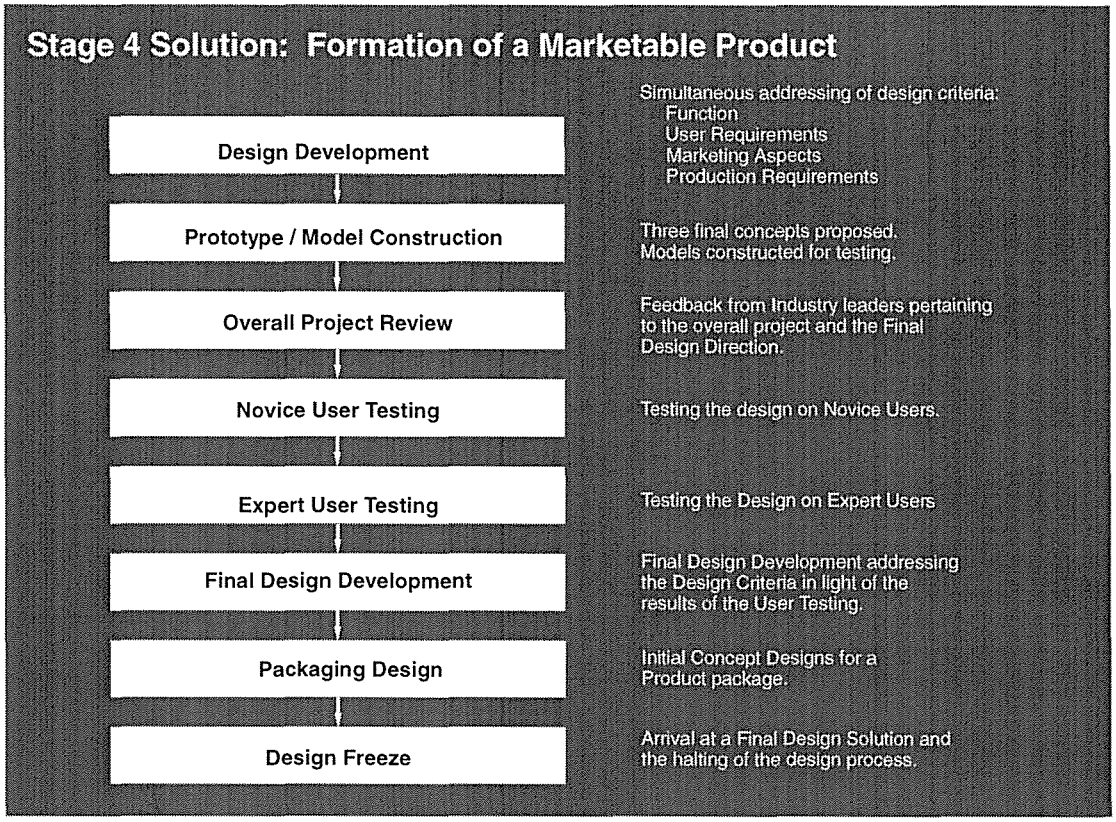


Figure 49 The Design Process.

5.1 Research: Establish a User Approach

The lead up to this project commenced in mid 1993 with initial reading into the field of laparoscopic surgery. After several months of general investigation and literature reviewing, the problem of tissue extraction in endoscopy was brought to my attention. A proposal was draw up for the development of a tissue extraction system for endoscopy. Following this the project was formally commenced.

Research prior to formally commencing the project only provided basic knowledge of endoscopy. With no medical training, additional early reading was essential in establishing a knowledge base so that it became possible to effectively communicate with surgeons, pathologists, and other people within the medical industry.

Once the project had begun, extensive initial research commenced. A plan was drawn up to establish what research should be performed, and in which sequence. Two topics were researched in parallel: Define the User and Their Needs, and establish The Primary Functional Goals (Figure 50). The two topics were researched concurrently because a large percentage of the information gathered could be applied across both topics.

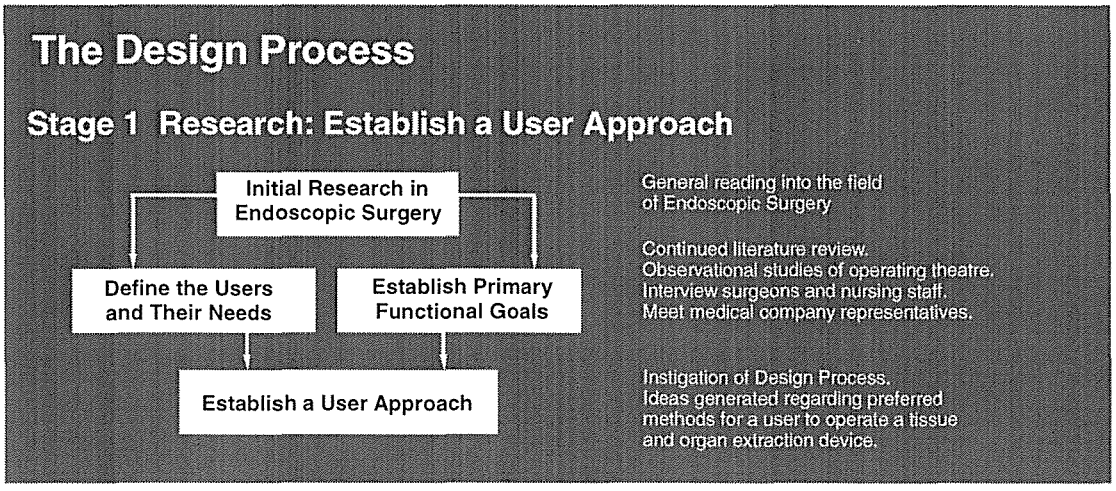


Figure 50 Stage 1 - The Design Process.

5.1.1 Definition of a User and Their Needs

Research Process

Observational studies were conducted within the operating theatre. Particular attention was given to operations involving the removal of an organ. Surgeons and nursing staff were both formally and casually interviewed. Over time an appreciation, and understanding of the working methods and thought patterns of the user group was attained.

Particular benefit was gained from reading "textbooks" for trainee surgeons, and papers describing how to perform a particular procedure. The instructions show the priorities and concerns of the physician as they are conducting the operation.

Research Conclusions

Surgeons would prefer to focus only on the actual treatment they have to perform. Their job involves substantial stress, and any additional anxiety brought on by poorly designed instruments is totally undesirable. The more complex and difficult an instrument is to use, the less attention a surgeon can focus on the actual treatment.

Surgeons must have confidence in their tools. A product with a lower assurance of reliability reduces the surgeons confidence and thus, will usually be interpreted by the physician as a product of lower safety.

There is little room for error in medical operations. A surgeon does not have the chance for a second go, or the opportunity to start again. As a result the physician must be 100% sure that each step is performed correctly. If a surgeon is not sure that a manoeuvre is going to work, then the situation will be reassessed until the physician is 100% sure that the next step will proceed exactly as desired. The result is that a surgeon will either perform a task with total confidence, or not perform it at all.

5.1.2 Essential Functional Goals

Research Process

To discover the functional goals that the instrument should fulfil, three sources were investigated. Surgeons were again interviewed and observed in

theatre, journal articles discussing organ extraction were gathered, and professionals within marketing, and research and development departments of medical companies were interviewed.

Research Conclusions

The essential functional goals identified were:

- Remove a large tissue specimen from within the patient.
- There should be no compromise of the endoscopic approach to surgery.
- The resultant tissue pieces must be suitable for pathological examination.
- The design concept should work in Laparoscopy and Thoracoscopy.
- There can be no risk of contaminating the operative site with the diseased tissue being removed.

In addition to this list, more specific design criteria were established as the project continued.

5.1.3 Initial Concept for the User Approach

Once the user and their needs had been defined, and the primary functional goals outlined, design concepts aimed at satisfying both sets of requirements were explored.

To establish a concept for the user approach, the problem was reduced to its simplest form. Exteriorise an organ from just under the patients skin. A parallel was drawn between withdrawing blood and removing an organ.

In a similar manner to the process of withdrawing blood, an organ could be removed - Insert the device, pull back on the plunger to extract out the organ, then remove the device from the patient.

This parallel established the user approach. To make a device which enabled an organ to be extracted in three steps (Figure 51):

1. Position the organ just under the skin,
2. Insert the device and capture the organ,
3. Pull up on the device to remove it and the organ from the patient.

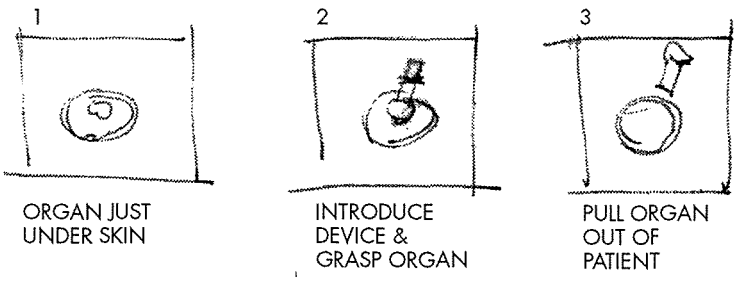


Figure 51 First Concept for User Approach.

5.1.4 Review of Methodology Used for Stage 1 - Research

Much useful information was gathered during this early stage. Several key contacts were made within the local community which proved invaluable throughout the entire project.

Prior to conducting an interview, notes and questions were prepared. A better planned structure for the questions may have achieved higher interview productivity. Similarly, better, more structured planning preparing for observation time spent in theatre, may have produced additional conclusions. Additional video footage of the operating theatre environment would have been useful.

The contacts formed with local medical companies could have been expanded upon encompass organisations interstate. It would have been an ideal opportunity to undertake work experience at a large organisation such as Johnson & Johnson, to benefit the project by:

- Improving my ability to access relevant and up to date information.
- Establishing links with large research departments capable of assisting or even joint venturing on the project.
- Increasing access to highly specialised and internationally experienced individuals suitable for providing suggestions and recommendations on the project.

5.2 Invention: Achieve Function

Once a concept for the user approach had been established, work commenced on the development of an invention. It was essential for the invention to be compatible with the user approach. At this early stage the user approach provided design direction and a target, it was not totally inflexible nor completely ignored. The aim of this part of the project was to produce an experimental working model, which achieved all of the essential functional goals. Once this had been achieved, the remaining design criteria could be addressed. The only non-performance related criteria to be continually considered, was the limited available resources

The overall process of achieving a working model was by far the most difficult, lengthy, and at times demoralising aspect of the entire project. The entire task took a full twelve months. The tasks conducted over this period involved a cyclic pattern of: development, trialing, and refinement (Figure 52). The lengthy time period was predominantly due to the need to make trial models, most of which could only be used for one experiment.

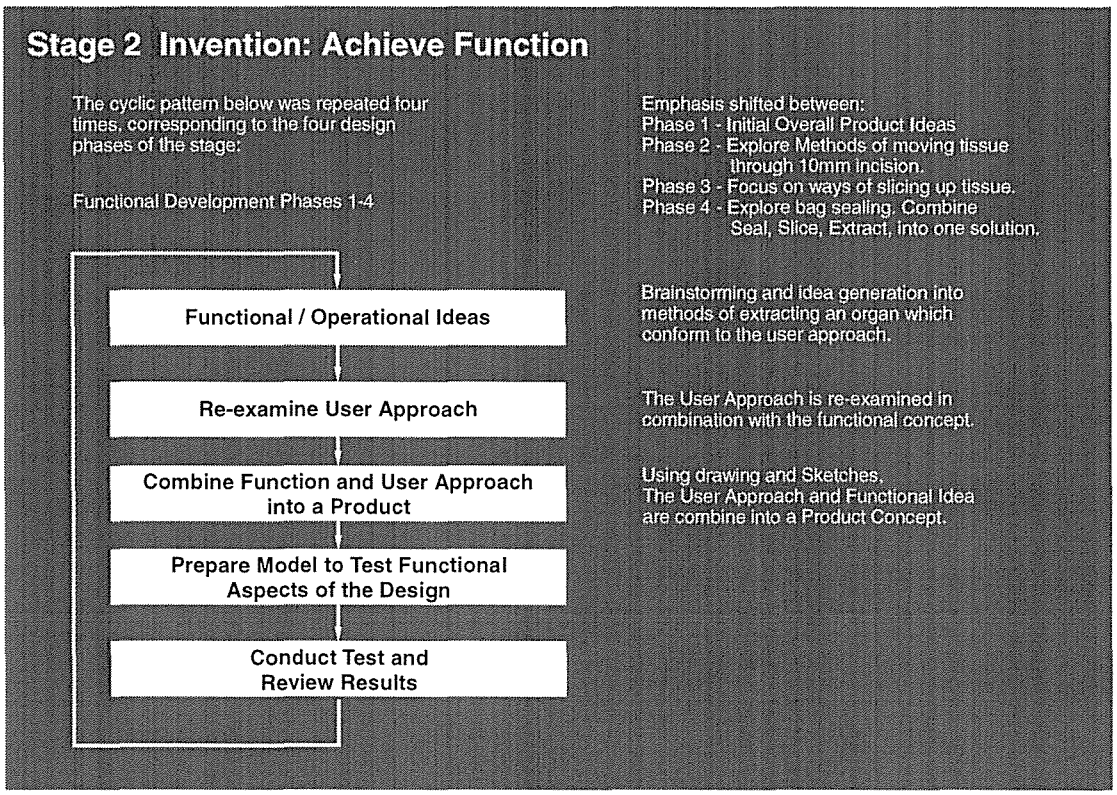


Figure 52 Stage 2 - The Design Process.

5.2.1 Functional Development Phase 1

Brainstorming method of design was used to generate ideas. Initial thoughts explored methods of removing the organ in a pulling action. A variety of encapsulation ideas, cutting methods, and extraction techniques were generated (Figure 53). The idea selected as promising was: to contain the specimen in a bag, then a number of fine wires would be pulled through the organ, lastly the entire bag and contents would be pulled through a funnel shaped opening. The entire process was to be performed in the one continuous motion of: Capture - Cut - Remove.

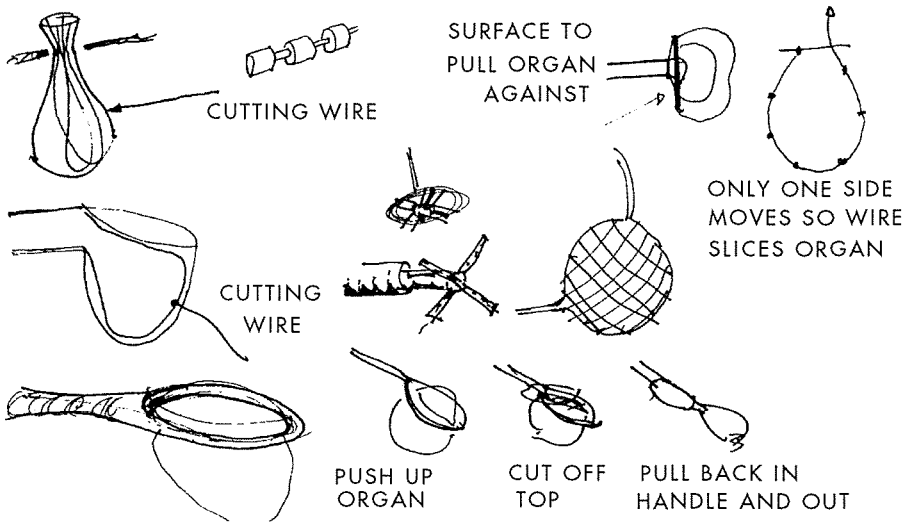


Figure 53 The Sketches of the Wire Concept.

The positive aspects of the concept seemed overwhelming. There were no sharp blades, the entire operation was incredibly simple and quick, the device consisted of few parts, it fulfilled almost every criteria - theoretically.

A modified user concept was explored. The overall operation of the device would still be performed in one action, but several levers or release buttons would be incorporated to increase user feedback (Figure 54).

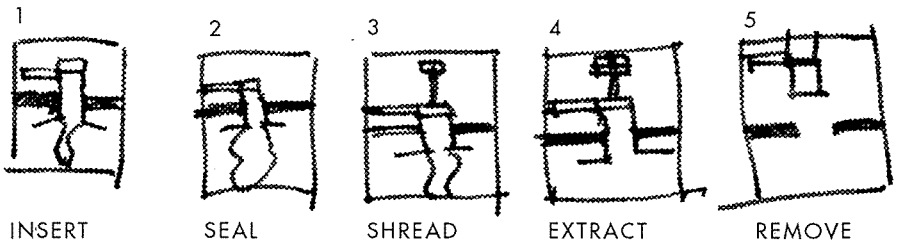


Figure 54 Stage 1 Redefined User Concept.

With both the mechanical requirements, and a user concept conceived, a few hours were spent exploring visual marketable product solutions. Deliberately, the illustrations produced were not excessively resolved, or overly fixed in design. The purpose was to provide a "vision" of where things may be leading (Figure 55).

A simple prototype was designed to trial these early ideas. Quick sketches were used to develop the model, then a scale drawing was made for production of the item. An acrylic handle was made, and an encapsulation bag was produced from a thin plastic film (Figure 55). Fine stainless steel fishing trace wire was hand tied to the inside of the bag using fine cotton. The ends of the wires were then glued to the handle.

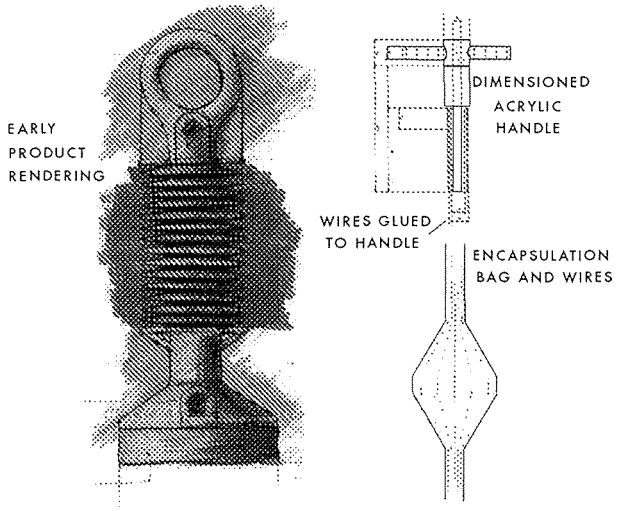


Figure 55 First Product Concept and Drawing of First Model.

Trial 1- Encapsulate, Slice, and Remove.

The basic procedure was (Figure 56):

1. A bullock kidney was placed inside the bag.
2. The bag was sealed off inside the handle.
3. The handle was grasped and the inside cylinder was pulled back, forcing the wires through the kidney.

The model failed to function as intended. The excessive force exerted when beginning to cut through the kidney vascular structure caused the plastic bag burst open. The wires did not cut through the sinus kidney vascular structure. The handle could not be controlled as intended, because the cylindrical shape was too small and difficult to hold steady.

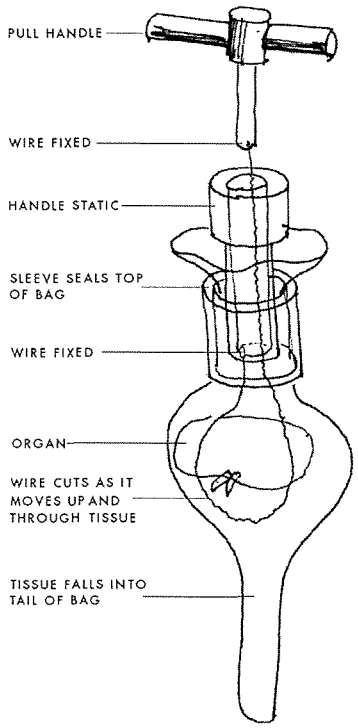


Figure 56 Intended Operation of Experimental Device.

Trial 2 - A Second Attempt to: Encapsulate, Slice, and Remove.

The design was slightly modified and a second trial was conducted. The bag dimensions were altered, a second handle was added, and an attempt was made to strengthen the bag.

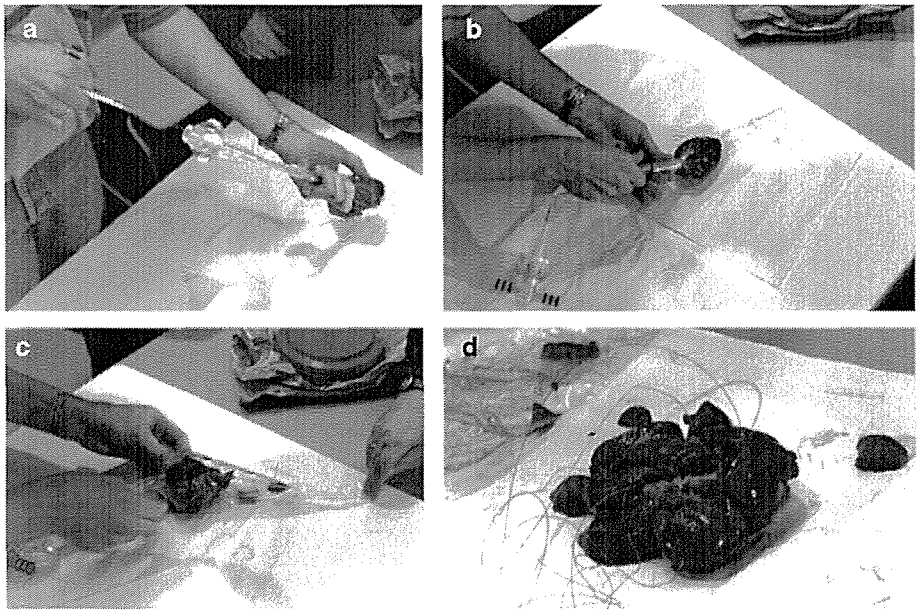


Figure 57 Second Trial.

(a). Bag Wires Handle, (b). Handle still impossible to control, (c). Bag burst again, (d). Organ began to be sliced up but wires still became stuck.

The handle of the device had been enlarged, however it was still impossible to simultaneously control both the bag/organ and the handle (Figure 57a, p153, Figure 57b, p153). The bag was not strong enough and burst again (Figure 57c, 153). The wires began to slice up the specimen, but still became stuck in the vascular structures of the kidney (Figure 57d, 153).

5.2.2 Functional Development Phase 2

The key problem identified with the first two experiments was that too many variables were being trialed simultaneously. It was decided to break down the trials into smaller experiments, each focusing on only one aspect of the design. The three aspects for exploration being:

- 1. Sealing up the bag
- 2. Cutting up the specimen
- 3. Removing the specimen from the patient.

The User Approach was re-examined and ideas were sought on how to operate and control a sealing, slicing, and extraction mechanism (Figure 58). Two new ideas emerged: Cutting the wires with a twisting action, and removing the specimen with suction assistance. Several ideas on sealing mechanisms were briefly explored diagrammatically, but all were found to be dependant upon the characteristics of the slicing and extraction mechanisms. Sealing mechanisms were left for exploration at a later date.

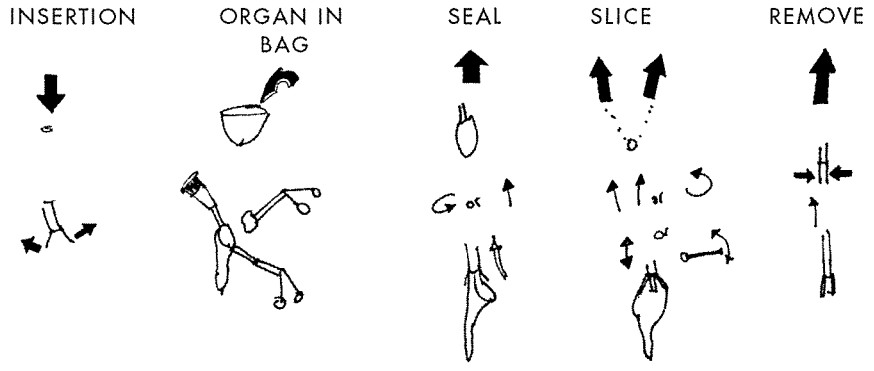


Figure 58 Re-examination of User Approach and Control Issues.

The Larger Arrows Represent the Overall Motion of the Product, while the Smaller Arrows Suggest the Possible Motion of a Users Hand.

Trial 3 - Slicing By Turning

A third experiment was carried out to trial if the specimen could be sliced by turning the handle so that the wires twisted into the specimen. In this experiment the wires were fixed to the bag using adhesive tape. The wires did not cut through the specimen before the turning forces began greater than could be exerted by manual hand rotation. The idea was abandoned.

There was a need to establish the maximum size of the specimen to be extracted. In Section 2.7.1 p72, it was determined that an extraction device must operate through a 10mm or smaller surgical port. On this basis the maximum possible size that could fit through a 10mm surgical port would be 10mm diameter strips. The only additional constraint of this would be the capabilities of the tissue extraction mechanism. For this reason it was decided to finalise the extraction mechanism before continuing development of the slicing mechanism.

Trial 4 - Suction Through a Funnel

A funnel was turned out of acrylic. The funnel reduced from an inside diameter of 50mm to an inside diameter of 10mm over a length of 60 mm. The funnel was fixed to the end of a yabby pump. A kidney pre sliced into 8mm x 10mm was placed inside a plastic bag and taped over the mouth of the funnel. Suction was applied in an attempt to suck the tissue through the funnel into the yabby pump. This was tried with the pump in an upside down position, horizontal position, and upright position.

When in the upside down position all the tissue was removed. In the horizontal position 90% of the tissue was removed but some pieces became trapped in plastic folds against the inside of the cone. In the upright position only 50% of the tissue was removed before the bag became folded on itself and jammed.

The idea was considered promising and was retained for further exploration.

Trial 5 - Extraction By Force

Samples of dacron and kevlar fabrics were obtained to construct a stronger bag. A longer thin bag was constructed using an inner layer of smooth polyethylene and an outer layer of dacron (Figure 59). All previous bags had been heat sealed along the edges, however this one was sewn for added

strength. A pre sliced kidney was placed inside the bag, and an attempt was made to pull the bag and contained specimen through the acrylic funnel.

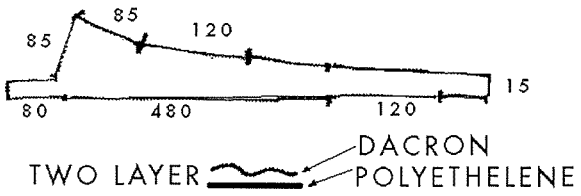


Figure 59 Strong Dacron / Kevlar Bag.

The experiment was partially successful. Some tissue was exteriorised through the funnel, but not all as the bag jammed. The force required to pull through the entire bag could not be achieved. The entire bag length was too large to be manipulated inside a body cavity.

Based on the results of trials 4 and 5, a solution, involving the combination of both suction and force, was considered. It was reasoned that by applying force to the bag, there would be no opportunity for folds in the plastic to form and block the funnel.

Trial 6 - Combining Force and Suction

Performed very similarly to the previous suction experiments, this trial used a pre sliced kidney, plastic bag and yabby pump. An assistant, using his/her hand, applied force to the bottom of the bag, while suction was applied with the yabby pump (Figure 60).

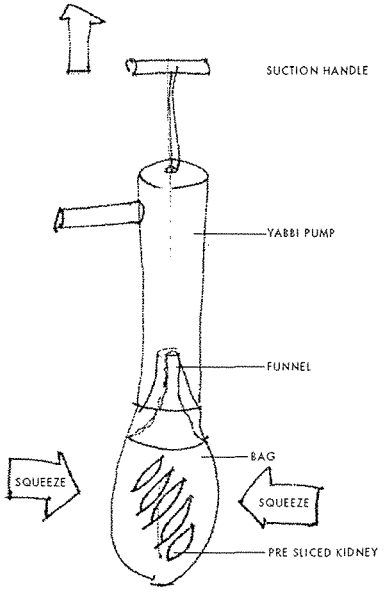


Figure 60 Combining Force and Suction.

The trial was successful. Large pieces equivalent or even slightly larger than the funnel opening (10mm) could be removed. It was decided that this was the solution to extraction of the specimen, and that attention could now be refocussed on cutting up the tissue.

5.2.3 Functional Development Phase 3

The third phase of functional development readdressed the problem of slicing up the specimen.

In keeping with the user approach, exploration was conducted into slicing the organ in a single upward motion. As discovered in early experiments, tissue can be tough, and wires cannot be pulled through the specimen using only manual force. In response to this, a way of increasing the pulling leverage was developed. By adapting the way a nut and bolt work, a rotating handle and a threaded rod can be made to produce a large upward pulling force. The idea was modified to fit the user approach and a test model was constructed (Figure 61).

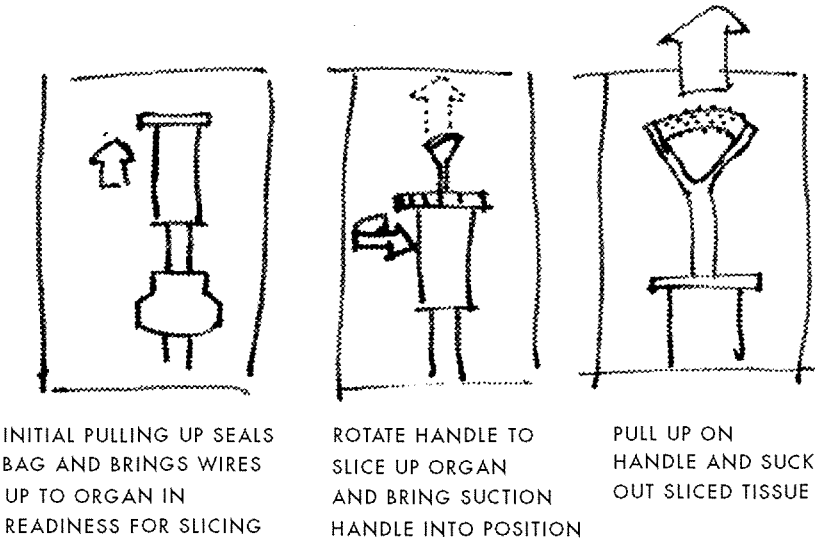


Figure 61 User Approach of Slicing by Pulling Only.

Trial 7 - Slicing By Pulling Only

Approximately 12 fine cutting wires were secured to the end of a 300mm length of threaded rod using adhesive. An acrylic tube was capped at one end and left open at the other. The threaded rod was drawn up inside the tube , through a hole in the capped end of the acrylic rod, and suspended in place using a large nut. A kidney was placed inside the wire loops attached to the opposite end of the threaded rod (Figure 62).

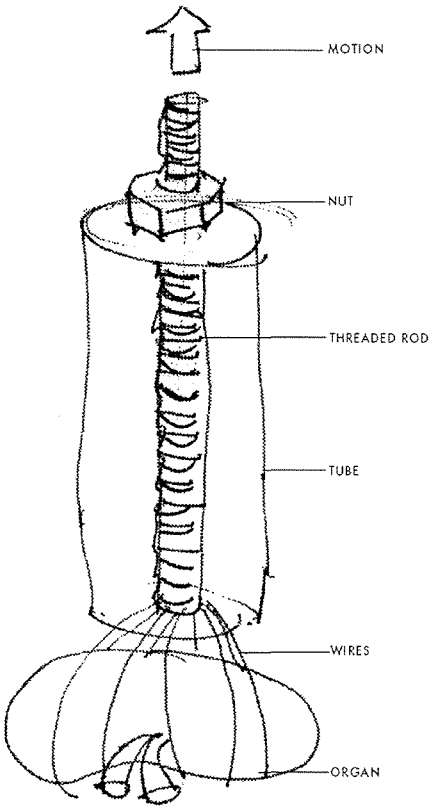


Figure 62 Trial 7 - Slicing By Pulling Only.

The organ was held in place by an assistant until the wires became taught. The nut was rotated, drawing the threaded rod and attached wires up inside the acrylic tube. As the wires cut deeper into the specimen, the force on the nut increased, to the extent that a 300mm spanner had to be used to rotate the nut and pull the wires completely through the organ.

All of the vascular structures had been torn and ripped out of the softer visceral tissue in one large lump. As result the specimen quality was very poor and would not be acceptable for pathological examination. Another second major problem which emerged concerned the large force required to cut through the tissue. Where such large forces are in use, a mechanical instrument failure is almost impossible to control, and certainly unsafe for use

inside the chest or abdominal cavity of a patient. If a highly tensioned wire snapped, it could cut through the bag, and cause seriously fatal damage to near by arteries, or organs.

The basic outcome of trial 7: The specimen will have to be "cut" into slices, as forcing wires through the organ fails to safely produce a specimen in an acceptable pathological condition.

Applying a pulling force alone to the wires will not satisfactorily cut through a specimen, however if a pulling force is combined with a sawing action, then the cutting force required would be reduced. A new product concept, using the combination of sawing and pulling was visually explored (Figure 63). The exploration was again only brief, aimed specifically at providing a possible visual direction for the project.

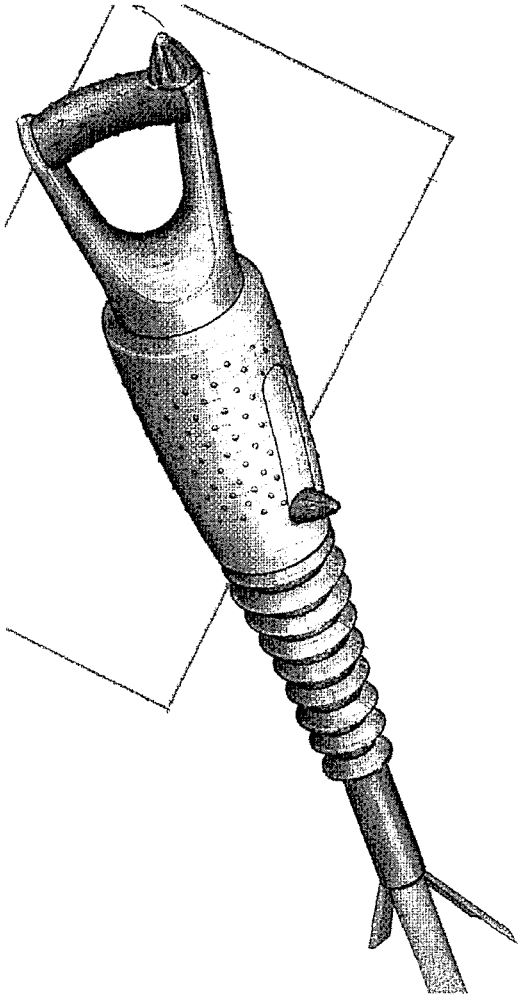


Figure 63 Product Concept With Sawing Action.

There were three main criticisms of this concept:

- 1. The semantics are inappropriate, giving the device the visual qualities of a jackhammer.
- 2. The turning action to achieve sawing does not reflect the mechanical function of the device.
- 3. The ergonomic qualities of the controls are poor.

Trial 8 - Slicing By Sawing

An experiment was planned to cut through the wires using a sawing and pulling motion. Figure 64 shows the equipment set up and concept of operation.

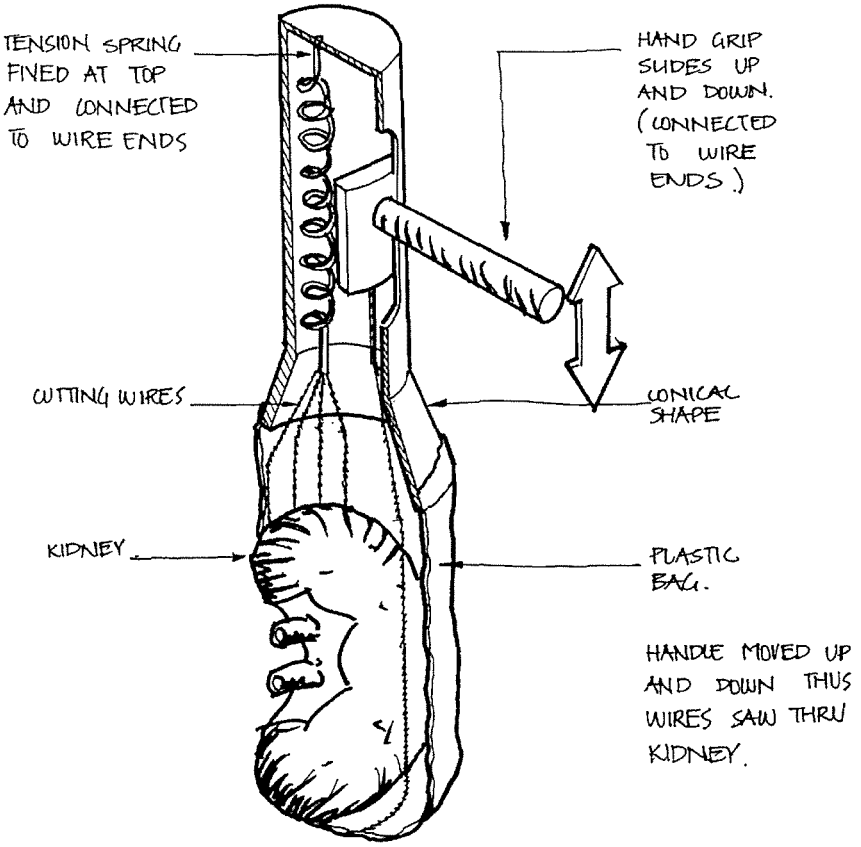


Figure 64 Slicing By Sawing.

A porcine kidney was placed inside the bag and the spring was tensioned. The sawing handle worked for one stroke before breaking. This proved to be a major achievement rather than a failure. The entire sawing mechanism was discarded in frustration, leaving only the bag and the grouped wire ends. While an assistant grasped the neck of the bag, the two wire clumps were

moved back and forth in a sawing action. The kidney was sliced neatly, simply, and quickly. A solution to slicing up the specimen had been found.

5.2.4 Functional Development Phase 4

The objective of the fourth phase of the development was to design and construct a mechanism for sealing the bag, and combine this mechanism with the suction requirements and the sawing requirements.

Using a design by analogy, initial ideas for sealing were investigated. Designs based on the concepts of the following already existing articles were explored: zippers, buttons, velcro, resealable plastic bags, and, electronic cable ties (Figure 65). In addition, other concepts of sealing up a bag were explored. The technique selected for development involved wedging the bag end between two concentric cones.

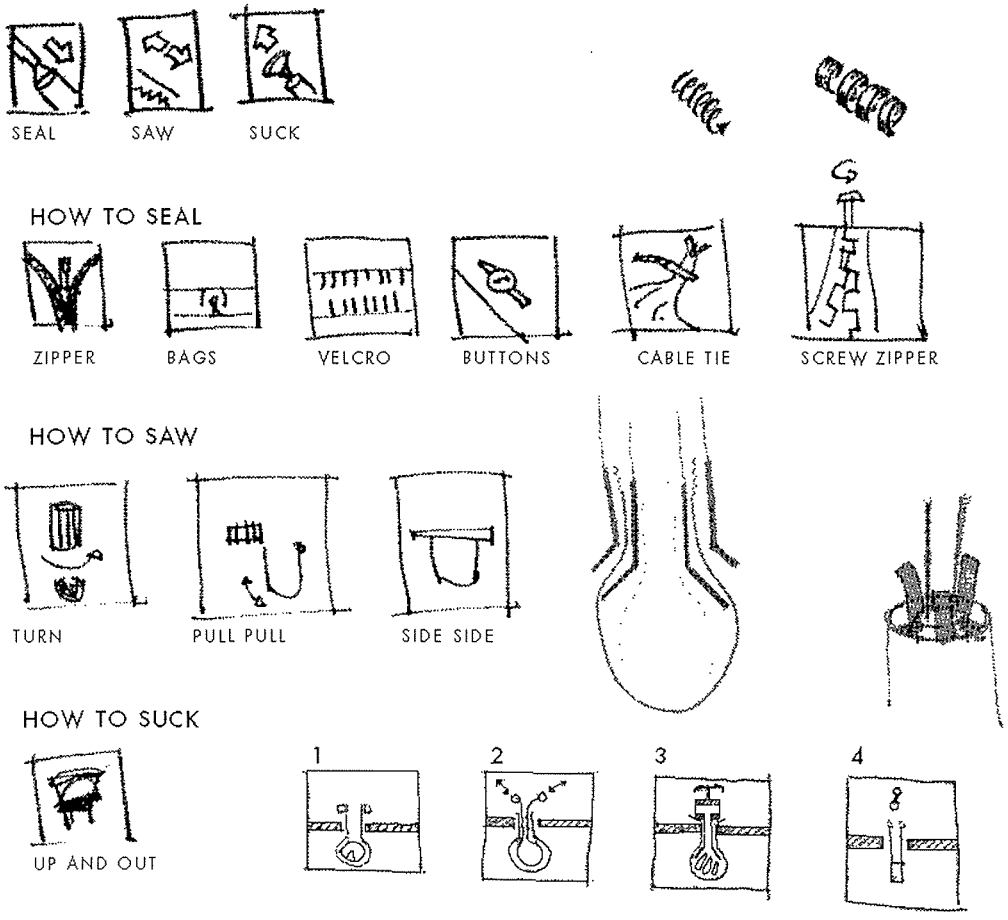


Figure 65 Exploring Sealing and Joining Mechanisms.

A physical model was developed for the combining of all three functions into one trial product. The trial model would encapsulate the organ, seal off the specimen, slice it into strips, then suck out the tissue. This did not represent the user approach, it represented the way in which the model was going to work.

The proposed method of sealing could not be tested until the dimensional constraints of the bag size, wire thickness, and the suction mechanism were defined.

The required bag size was obtained from sizes used by similar products currently available on the market. Initial size was 95mm x 150mm, constructed of a strong, woven, and impermeable material. It was estimated that the device would use approximately ten light weight stainless steel strands to slice up the specimen.

A series of trials (Trials 9 - 14) was planned to determine the physical constraints imposed by the suction process.

Trials 9 -14 - Determining the Physical Constraints of Suction

The trials aimed to answer questions such as: What shape and size will the entry cone have to be? Can we extract 10mm diameter tissue samples, if not what is the largest size that can be achieved? What characteristics must the bag possess to aid reliable suction? Are there any other functional features required to make suction work?

A test implement of reasonable quality was constructed to perform these experiments (Figure 66). Porcine kidneys were pre sliced into strips and placed inside plastic bags. The bags were attached to the acrylic funnel and inserted into the yabby pump. Using the pump in an upright position, suction was applied to the specimen, and the results were noted. The size of the tissue strips, the length of the extraction tube, and the shape of the entry cone was varied. Lubricant was used to further improve tissue removal through the extraction tube.

The essential conclusions of the trials were:

- Varying the extraction tube length between 80mm and 200mm did not greatly affect the ease at which tissue could be retrieved.

- Tissue slices not greater than 8mm x 6mm in cross section were desirable.
- The tissue slices must be firmly held against the entry cone for suction to work.
- Filling the bag with fluid prior to sealing and suction improved retrieval reliability.
- A smooth curved entry funnel is more desirable than an angular shape.

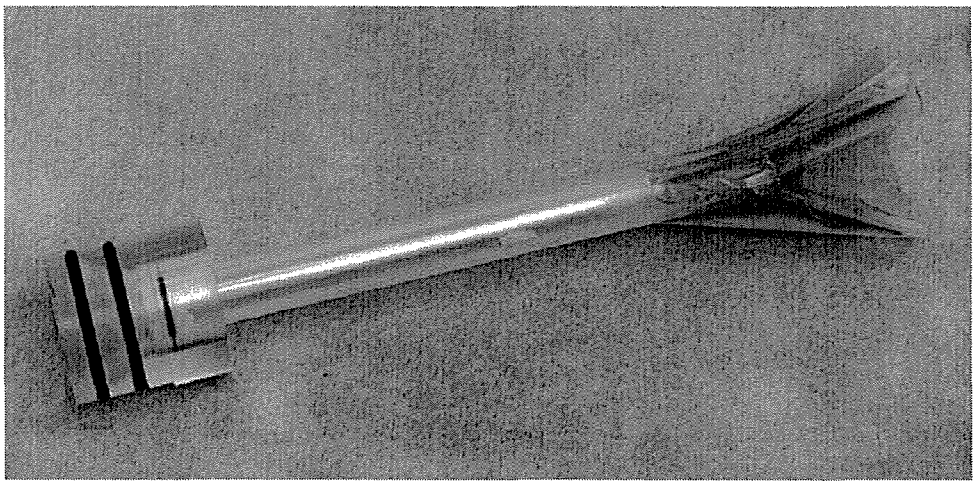


Figure 66 Testing Implement.

Using the results from trials 9-14, attention was again directed toward sealing off the bags. Two more experiments were developed to determine if a plastic bag of 95mm x 150mm could be slid between two concentric cylinders and sealed off.

Trials 15-16 - Feasibility of Sealing Between Concentric Cylinders

A large cylinder with an inside diameter of 15mm was cut at a length of 160mm. A smaller cylinder with an outside diameter of 12mm was cut at a length of 200mm. Employing a wide variation of folding and rolling techniques, the plastic bag was wrapped around the inside cylinder. The larger cylinder was then slid over the top of the smaller cylinder and plastic bag.

It was found the larger cylinder would only fit over the smaller cylinder if the bag was wound up very tightly and very neatly. It was impossible to draw the bag up inside the large cylinder and push the smaller cylinder down into the bag.

The conclusion: The bag must be wound up neatly to enable a seal to slide into place.

The problem of sealing the bag was readdressed. Possible alternative approaches, and methods for rolling up a bag tightly within the confines of the peritoneal or thoracic cavity were explored. A substantial amount of time was invested in designing and testing ideas, however a satisfactory solution was no found.

It was decided that the constraints were extremely tight and that a simple, and reliable solution was not going to be found in the remaining time period. Much attention and energy had been expended to try and arrive at a solution which sealed, sliced and sucked. Perhaps too much emphasis had been placed on trying to arrive at a solution which allowed all three to be performed in an automated fashion. Through the combination of gathered knowledge, and a looming deadline, a strategic switch in direction occurred (Jones, 1980). This change in direction was achieved by significant simplification of the functional components of the design, and a turn away from an intricate mechanically automated device.

The user approach (Figure 67) was modified to:

1. The organ would be placed inside a bag.
2. The neck of the bag would be exteriorised.
3. Handles would be attached to fine wires, which would slice through the organ in a sawing action.
4. Forceps would be employed to remove the tissue pieces.
5. The empty bag would be removed.

The problems of sealing and suction had been eliminated. The reliability of the slicing wires remained as the only mechanical problem to be solved. Once the concept was tested and working properly, automated suction, and internal sealing could be rethought and reapplied to the device (if required).

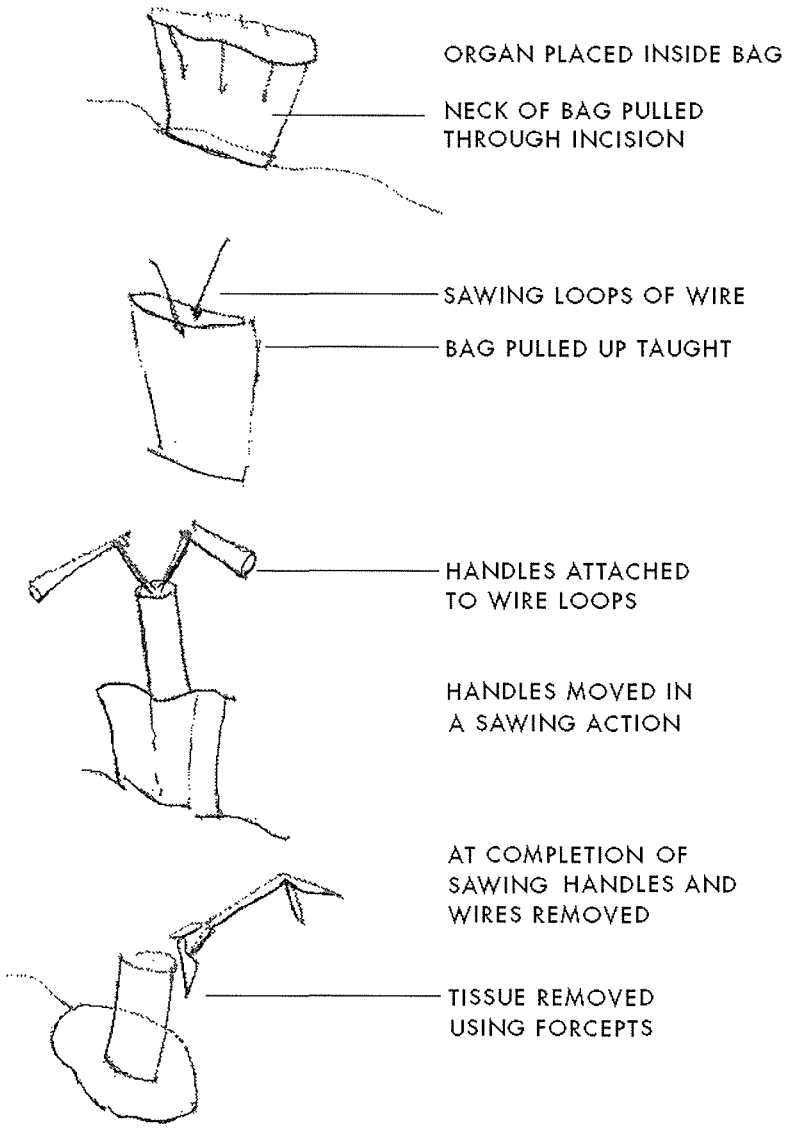


Figure 67 Revised User Approach and Functional Characteristics.

5.2.5 Review of Methodology used for Stage 2: Invention

A large volume of work was performed during stage two, and a simple design solution had begun to emerge.

All trials and experiments provided useful results, however better strategic planning would have significantly reduced the time taken to achieve a similar result. Individual series of trials were only planned on a one by one basis. A wider more overall strategy for trialing should have been drawn up and continually referred to and updated.

Documentation and recording of experiments was performed using notes, drawings and photographs. More photographs should have been taken. Video

recording should have been utilised, and more extensive notes should have been recorded. By improving the recording and observation processes, the overall design process would have been made more efficient. Two specific and very significant temporary oversights would not have occurred:

- In the initial trials 1-2, the tissue had begun to be cut very well by the initial sawing action of the wires. The large number of problems and issues arising out of the trials disguised this partially successful feature, and thus a key functional characteristic remained unseen until trial 8. Had video observation been utilised post experimentally, this feature may not have remained unseen.

- Throughout this stage, and the later stages of the development process, the problem of bag splitting and bursting was continually encountered. A solution to this problem was found in Trial 5, p155 with the construction of a fabric bag lined with plastic. This very strong and reliable method of bag construction was overlooked until much later in the design process.

5.3 Definition: Specify User Approach and Product Function

Following the developing of a functional idea, the project began to take on a more convergent approach. A number of tests were performed to evaluate the functional concept. At this stage the user approach became defined, and a specific way of operating the device was established. The aim of this part of the project was to produce a specific design direction, with essential functional elements and components (Figure 68).

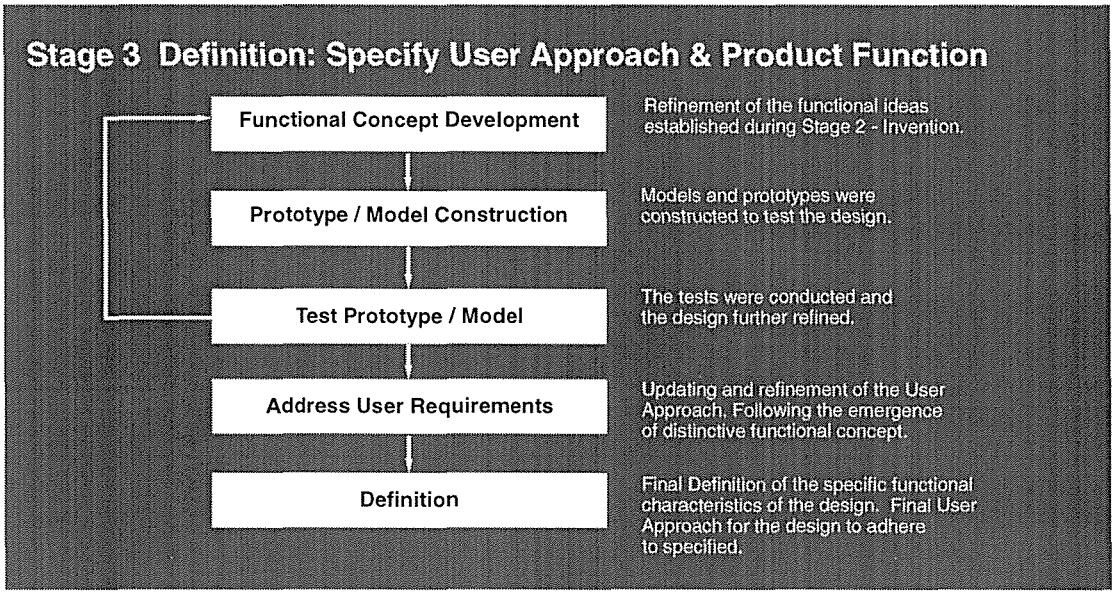


Figure 68 Stage 3 - The Design Process.

5.3.1 The Latex Model

Attaching wires to the inside of the entrapment bag had been a difficult and time consuming task. The wires had always been stitched, or taped into place. Due to the large number trials being performed it became desirable to find a faster and simpler method of securing the wires in place. A latex bag was conceived, in which the wires could be moulded directly into the sides of the sac (Figure 69). The latex was strong enough as to not burst during the morcellation process, and the elastic nature of the material would help the extraction of the tissue fragments.

A "male" mould was constructed from polychloroethene (PVC). Wires were attached to the mould and the their ends crimped together to form loops, for attaching to the morcellation handles. The mould was dipped in a bucket of latex many times until a wall thickness in excess of 1.5mm was achieved.

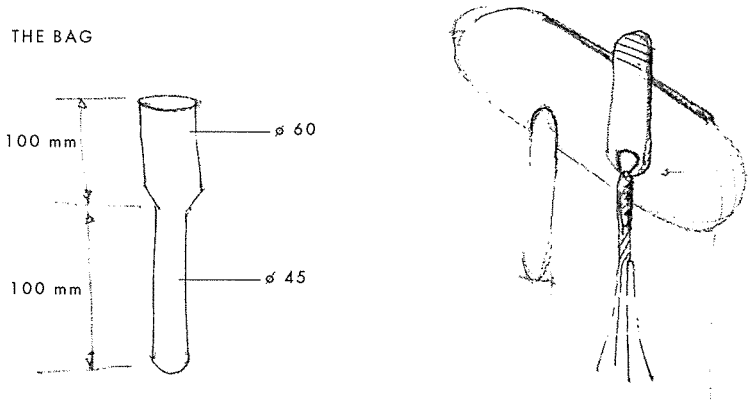


Figure 69 Sketches and Detail Drawing of the Mould.

A morcellation handle was designed and constructed out of aluminium (Figure 70). By turning the knob at the end of the handle, a hook was exposed which secured the loops formed by the crimped wire ends. Time was taken to construct a high quality implement , suitable for presentation to industry representatives.

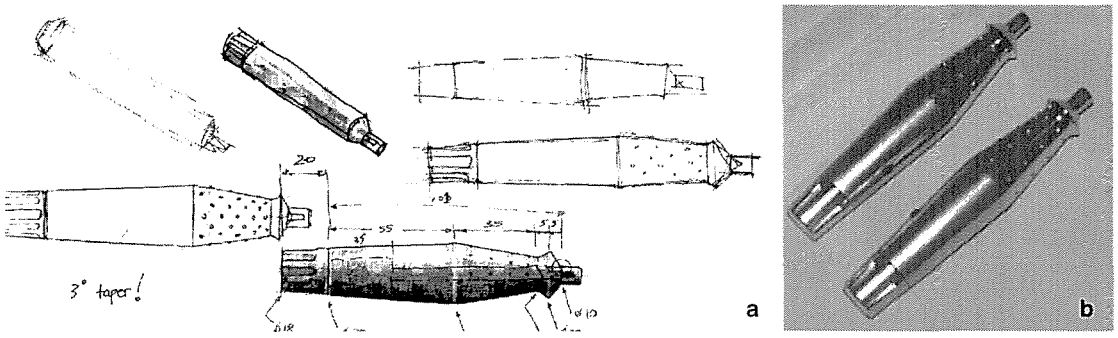


Figure 70 Morcellation Handles: Design, and Constructed.

Trial 17 - Latex Bag One

The aim of this first trial was to see if the wires would release from the side of the bag and slice up a porcine kidney into even pieces of a suitable size.

A mock up "abdomen" was formed out of latex approximately 250mm in diameter and 5mm thick. A 12mm diameter hole was cut into the centre. The abdomen was wrapped around a wood frame, thus forming an elastic and stable facia, representing the abdominal or thoracic wall of a patient. A 15mm

Surgiport (AutoSuture) was inserted into the abdomen. The latex bag was inserted down the port. The kidney was placed inside the bag. The port was removed and the neck of the bag was drawn out the incision. The morcellation handles were attached to the wire loops and the bag and contained organ were pulled tight against the abdomen. Force was applied to the handles in a sawing action. The force require to release the wires was too great and the test was suspended.

The quantity of latex holding the wires in place was excessive and had to be reduced or the wires had to be partially pre-cut from the bag prior to use (Figure 71).

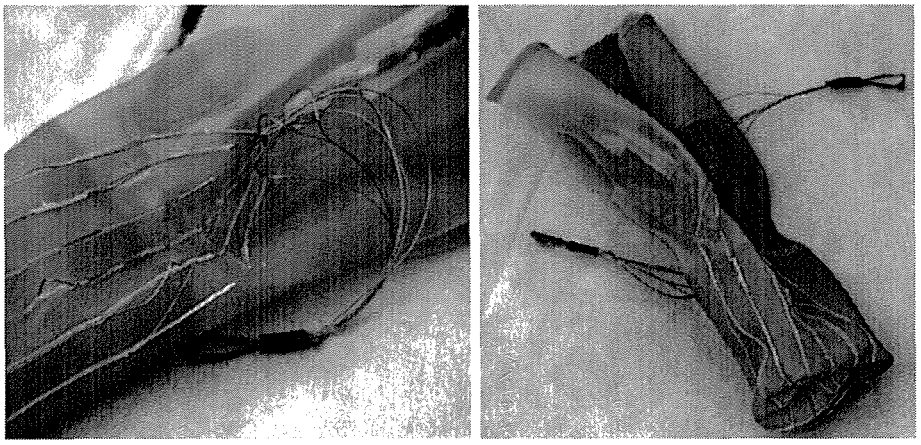


Figure 71 Wires Unreleased From Latex Bag 1.

Trial 18 - Latex Bag Two

Trial 18 was conducted in an identical manner to trial 17. The only alteration was the partial pre-cutting of the wires from the latex bag.

The entire kidney was sliced into strips (Figure 72). The bag did not burst. The cutting action was performed without difficulty. The trial was a complete success. A model had been constructed which would work effectively and reliably.

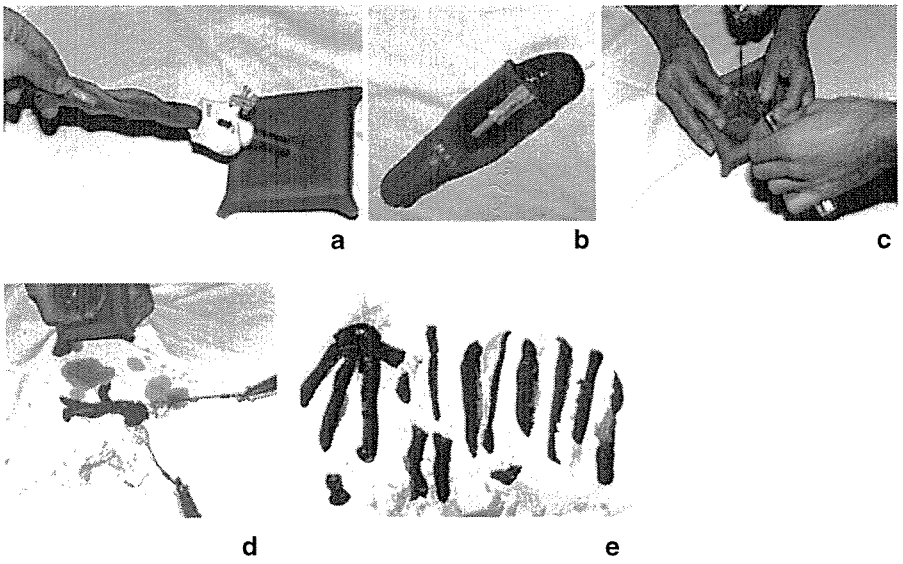


Figure 72 Trial 18 - Latex Bag No. 2.

(a). The Surgiport is Inserted into the Abdomen. The Bag is Rolled up and Inserted Down the Surgiport. (b). The Kidney is Manoeuvred into the Bag. (c). The Neck of the bag is Exteriorised, the Handles are Attached, The Specimen is Morcellated. (d). The Wires and Handles are Completely Detached after Morcellation. (e). The Resultant Tissue Fragments.

Trial 19 - Latex Bag Three

The third latex bag trial was an attempt to combine the new working bag with suction. A kidney specimen was sliced as in trial 17 and 18, then the acrylic funnel from trials 9 - 14 was attached to the opening of the bag. The sealed bag was filled with warm water to lubricate the encapsulated kidney and the funnel. The yabby pump was used to apply suction to the bag (Figure 73).

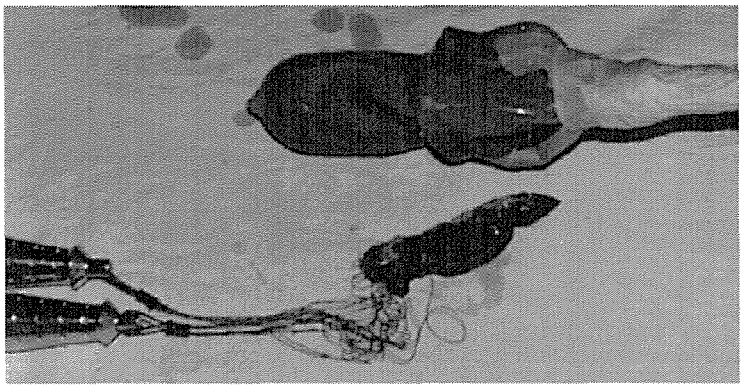


Figure 73 Applying Suction to a Sliced Specimen.

Not all of the tissue was removed. The bag folded over upon itself and the tissue strips clumped together and blocked the funnel. It was concluded that

the blockage was because the bag was not pulled tight enough prior to the application of suction.

To physically pull the bag taught prior to suction would have complicated the design again, however using conventional wall suction to remove pieces individually could provide an alternative to removing the fragments with forceps. The preferred option would have to be determined by the relevant users and experts.

5.3.2 Defining the User Approach

Attention was now focused on producing a user approach which successfully combined the functional requirements with the user requirements. Some basic design exploration was performed to provide a product concept which could be assessed by surgeons and other appropriate professionals. Diagrams and figures were used to explore variations in possible user interfaces and product component configurations (Figure 74).

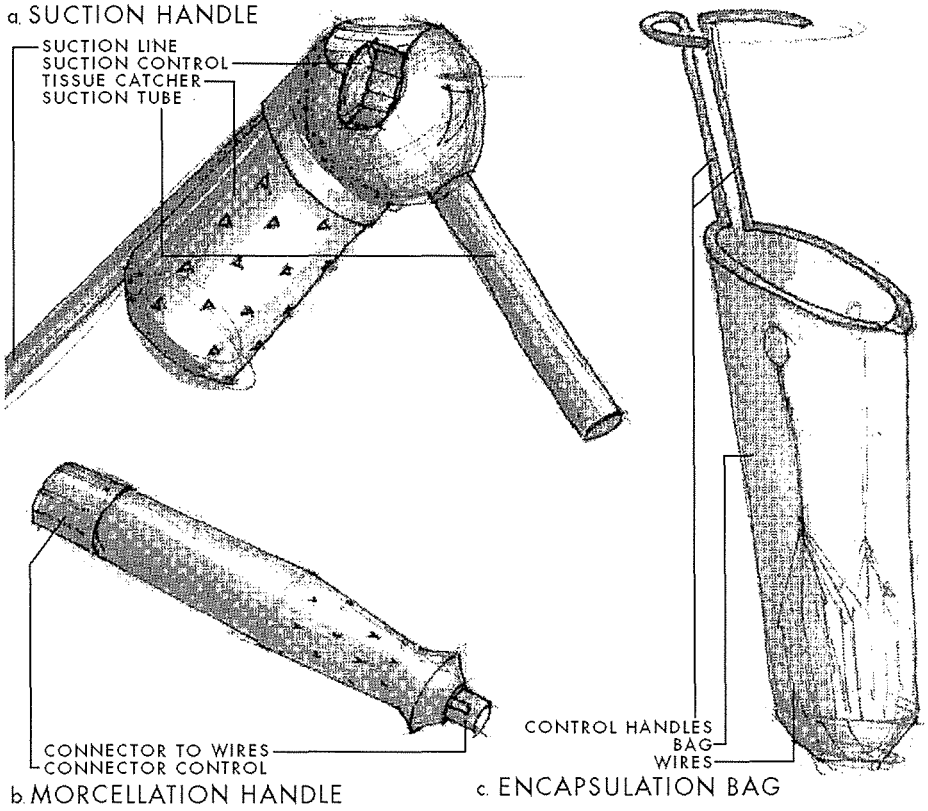


Figure 74 The First Product Concept.

(a). Tissue Retrieval / Suction Handle. (b). Morcellation Handle. (c). Encapsulation Bag.

The designs were shown to a surgeon, the head of a research and development department of the Australian division of an international medical company, and to the Industrial Design staff at QUT. Conclusions from the discussion were:

- Forceps would be preferred over suction for final extraction. Primarily because using forceps would be more reliable and less expensive than a special suction implement.
- The bag should come in a pre-package delivery tube to allow simple insertion and expanding.

Acting upon the feedback described above, the design was adjusted (Figure 75). This concept represents the basic steps to be performed when using the proposed extraction device.

The specimen for extraction will be mobilised by the surgeon

1. INSERT the device into the patient.
2. ENCLOSE and SEAL the specimen inside the encapsulation bag.
3. SLICE the encapsulated specimen.
4. REMOVE the resultant tissue fragments.
5. REMOVE the empty bag from the patient.

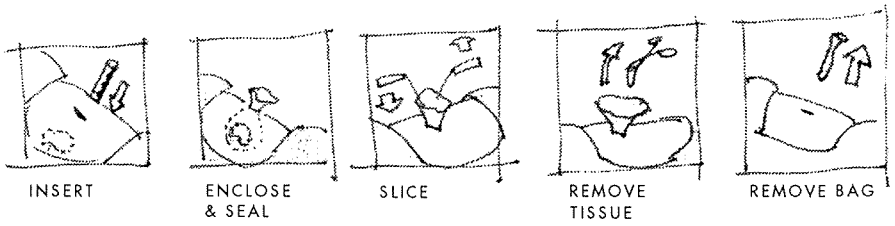


Figure 75 The Final User Approach

The Proposed Method for Using the Device (Illustrated Relative to the Patients Abdomen).

For two reasons the design began to concentrate on the production of a disposable product, rather than a reusable device:

- The functional aspects of the design require that the bag and cutting wires are integral and self destructive, making it physically impossible to reuse the bag or the wires.

- The major manufacturers of endoscopic surgical instruments produce disposable products, therefore to enhance the ability to on sell the intellectual property associated with the thesis, a disposable design was considered favourable.

5.3.3 Review of Methodology Used for Stage 3 - Definition

The progress of work during stage 3 was very rewarding. The aims of the stage were very specific and not difficult to achieve. Prior to commencing work on stage 3, a plan of attack was drawn up and strictly followed. Having a detailed and specific plan enabled the work to progress more effectively than in previous stages.

5.4 Solution: Design of a Marketable Product

With the function defined, and the establishment of a specific user approach, a marketable design began to emerge. A process of design development, followed by applied user trials were utilised in progressing toward the final design (Figure 76). As the design progressed, more detailed attention was given to each of the individual design criteria outlined in Chapter 4. In fact many of the criteria listed in Chapter 4 were identified while working on this stage of the project.

The packaging of the proposed design was considered immediately after the design freeze. It is important to point out that the time spent developing the packaging was very small in comparison to the energy and resources employed to develop the actual instrument. For this reason the proposed packaging should only be regarded as an early concept, rather than a final design.

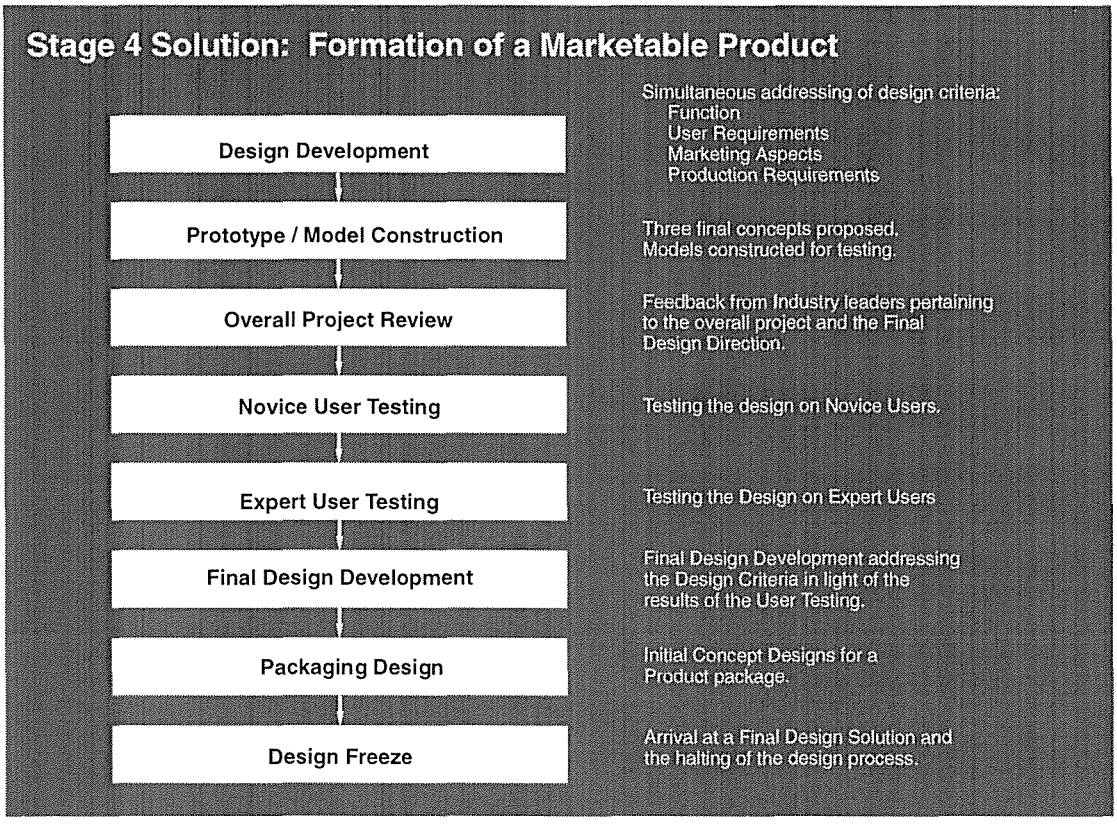


Figure 76 Stage 4 - The Design Process.

5.4.1 Design Development of the Encapsulation Bag

Design development was instigated on the encapsulation bag. The design needed to maintain the functional qualities of the latex bag, but improve the manufacturing and user characteristics.

Holding the Cutting Wires in Place

The latex bag was highly successful, but a more efficient way had to be found for attaching and releasing the wires. There were two problems associated with how the wires were attached to the latex bag: Firstly, the wires were difficult to hold in place during the moulding process, and secondly, the wires were actually fixed to the bag and required a large shearing force to pull them from the inner surface of the sac (with the potential to rip a hole in bag).

A multi layer bag, constructed from sheet thermoplastic was proposed. The wires would be heat sealed in pockets between a tough external layer and a very thin inner film. Manufacture would be simple, the wires could be laid between the two layers, and then the bag folded and formed into shape by heat sealing along the edges (Figure 77).

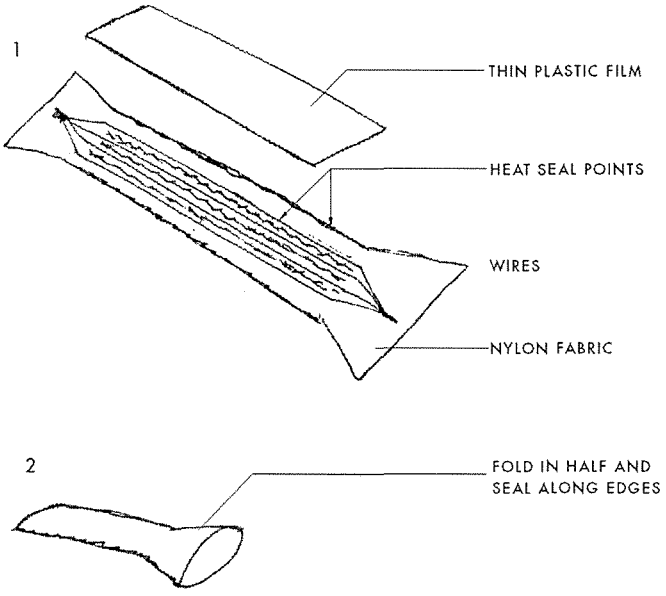


Figure 77 Manufacturing the Encapsulation Bag.

The wires would not be directly held to either the inner film or the outer layer and thus could move back and forth in a sawing motion. The wires would cut through the inner film without applying a shearing force and potentially tearing the external layer of the bag.

Size and Shape of the Bag

The size of the bag is directly dependent upon the size of the specimens to be extracted. There was not sufficient time or resources to do an extensive survey of the dimensions of human organs, so two sources of information were used to establish the required bag size. Firstly, the size of currently available entrapment bags was surveyed. Secondly, surgeons were asked about the currently available bags and how well they met their needs.

The result of the investigation showed that the Ethicon Endosurgery Bag of 100mm x 100mm is well suited to the extraction of all organ except extremely inflamed spleens. For such large specimens a Cook LapSac, 140mm x 210mm is typically used. Therefore the proposed design will be equivalent in size to the Ethicon Endosurgery bag, and the final design solution should be available in larger or smaller bag sizes as required.

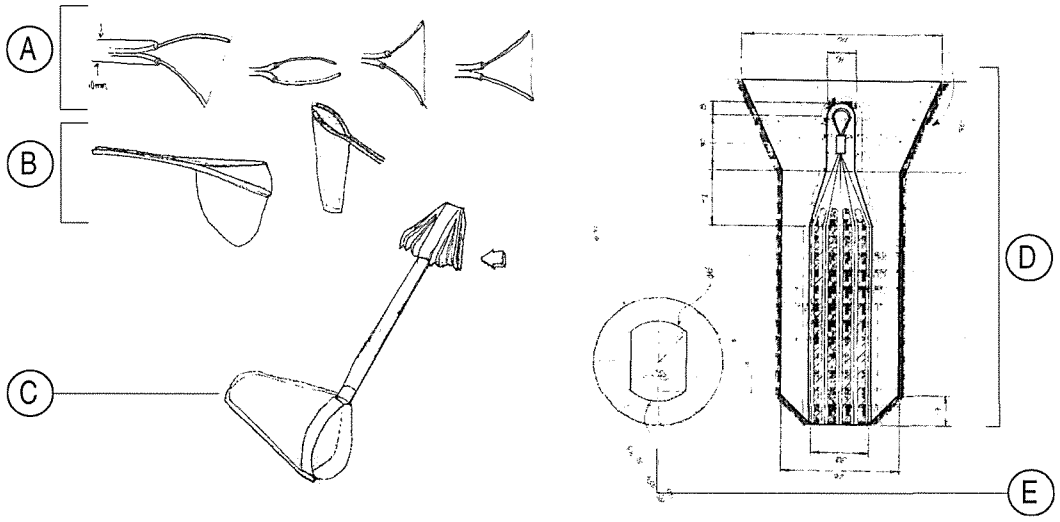


Figure 78 Size and Shape of the Bag.

Exploration of a Ridged Edge for the Bag Mouth using: (A) Wires. (B) Plastic. (C) Inflation with Air. The Proposed Bag Design: (D) Top View. (E) Section View.

The task of manoeuvring an organ inside a bag is difficult and takes considerable skill (Nathansen, 1995; Fielding, 1994; Fazzarlari, 1996), therefore the bag shape was developed to allow the easy capture of mobilised organs. The mouth of the bag was enlarged, forming a funnel to capture the organ. Ideas were investigated for forming a ridged edge around the mouth of the bag (Figure 78). The ridged edge would improve the manipulation of the bag and prevent the opening from folding closed while trying to insert an organ.

The proposed design would use a highly elastic, ridged plastic moulded to the mouth of the bag to provide an edge for easy capturing of the organ.

Folding up the Bag for Insertion into the Patient

Once the required dimensions and shape of the bag had been established, a method of inserting the bag into the patient needed to be developed. The bag will be inserted into the patient through a 10mm cannula, therefore the bag must be able to be folded up and contained within a 10mm cylinder (Figure 79).

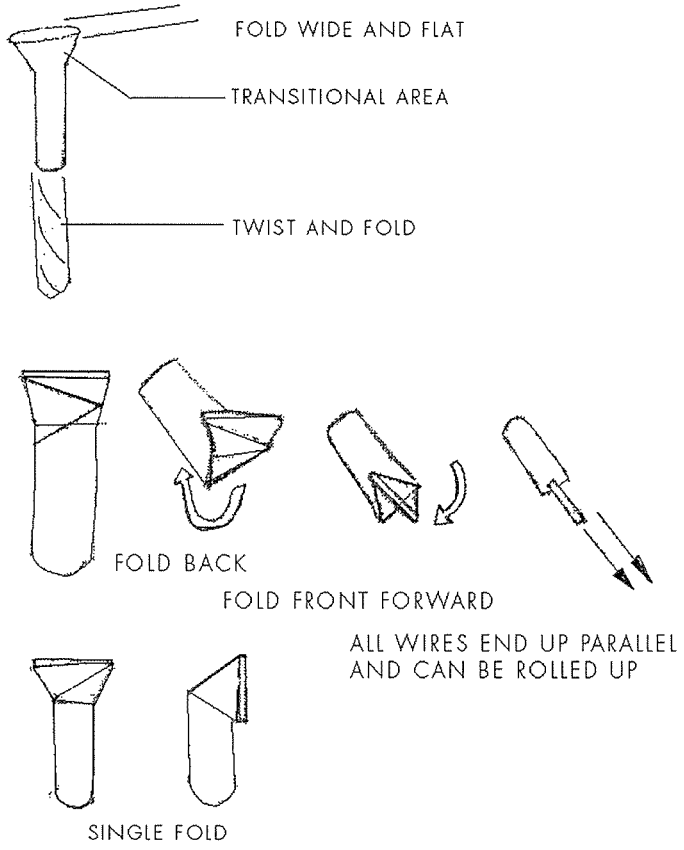


Figure 79 Investigating Folding of the Bag.

A model bag was constructed and folded up to test if it could be placed inside a 10mm diameter tube. The bag easily fitted inside the tube, however removing the bag from the tube became difficult. To solve the problem a lubricant was used, and as a result the bag could pass smoothly out of the tube and into the patient.

Trials 20-26 - Trialing the Wire Configuration

The designed configuration of the wires needed to be trialed. The wires had been laid out in a design which was intended to produce large tissue pieces capable of being pulled from the neck of a bag, which has been exteriorised out a 10mm trocar incision. Figure 82, p180, shows the intended cutting lines of the wires.

A concern arose about the possible cutting of the neck of the bag during the morcellation process. A guard was designed to alleviate those concerns (Figure 80).

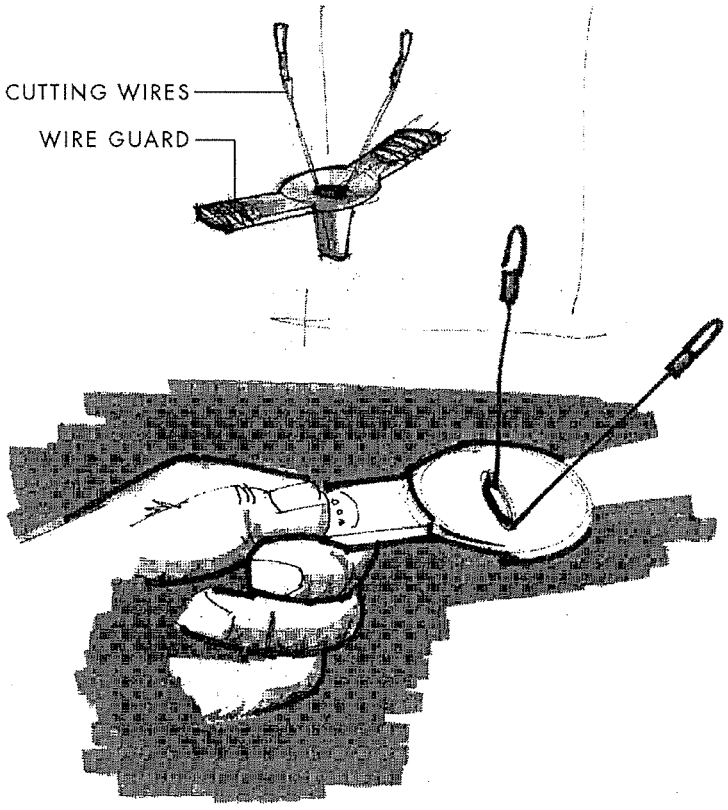


Figure 80 Proposed Wire Guard Design.

Prototypes of the bags were constructed. The outer layer was constructed of transparent plastic, the inner from thinner yellow plastic. The two layers were heat sealed together in a series of lines, creating passages for the wires to travel between. Once the wires were inserted the plastic strip was folded in half and sealed up along the edges (Figure 81).

The experiments were conducted in an identical manner to the latex trials, the only variation being the inclusion of the wire guard. A porcine spleen or kidney was inserted in the bag. The bag was exteriorised out the latex 'abdomen'.

The morcellation handles were attached. Force was then applied in a sawing action.

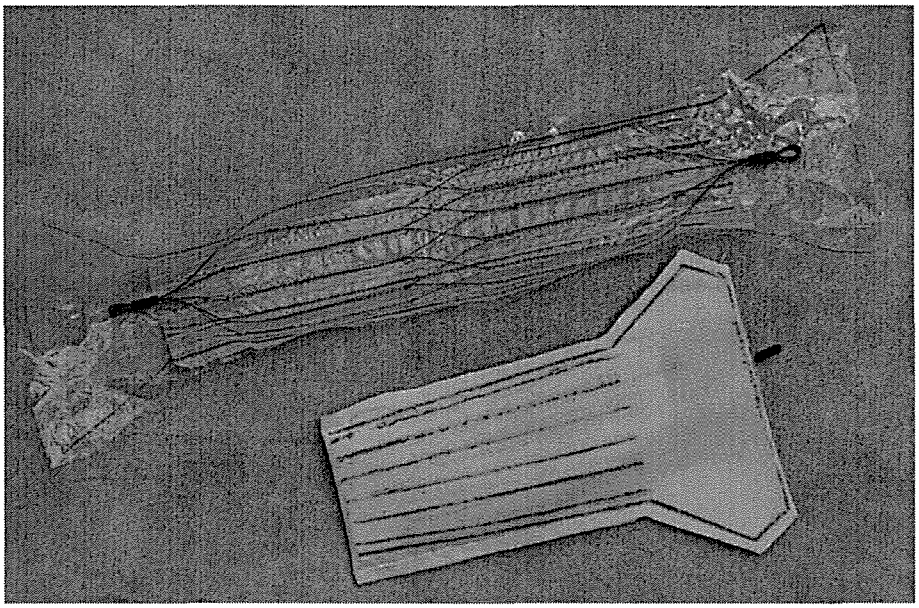


Figure 81 Construction of the Bags.

All of the bags burst and the experiments were regarded as a failure. The plastic chosen for the external layer of the bag was not strong enough to handle the forces generated during the morcellation process.

To solve the problem a light weight nylon fabric was sourced. The fabric could not be heat sealed but it could be sewn in place around the clear plastic layer. The bag now became a three layer design. For the final design a nylon would be used which could be heat sealed, and thus return the bag to a two layer configuration. The Cook LapSac is constructed of such a nylon, but unfortunately it was not possible to obtain any samples of the fabric suitable for prototype testing.

Trials 27-34 - Exploring New Wire Configurations

Four wire configurations were designed for trialing (Figure 82). The bags were constructed from two layers of plastic film with an outer layer of nylon fabric. Two bags of each design were constructed, so that in total eight tests were conducted.

The trials were conducted in the same manner as the latex bag tests, no wire guard was used.

The experiments were a great success. None of the bags burst. There were no slices in the necks of the bags caused by the wires cutting into the plastic. The second configuration (Design B, Figure 82) was chosen as the most successful as it most consistently produced tissue specimens consistent in size.

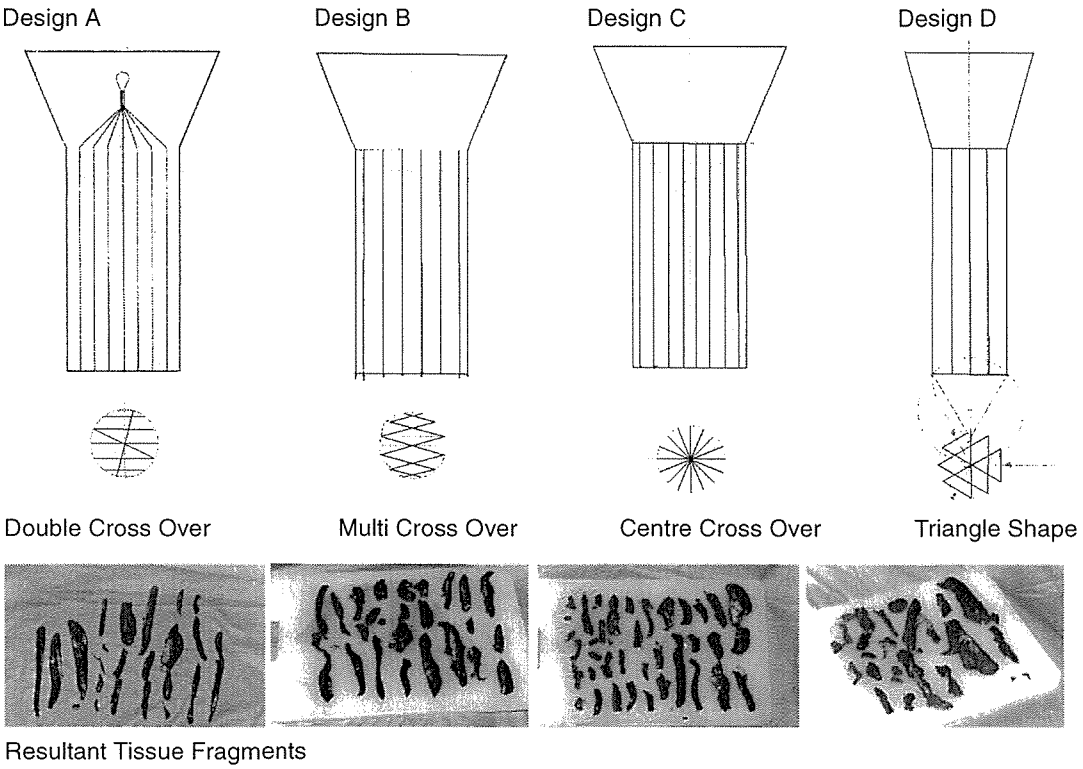


Figure 82 Four Wire Configurations and Resultant Tissue.

Trials 35-36 - Confirming a Guard is Not Required

Concern was still being raised that the cutting wires may slice through the neck of the bag and spill diseased cells at the incision site. Two trials were conducted which deliberately attempted to cut through the bag during the morcellation process.

A porcine kidney was placed inside a bag. The bag was exteriorised out through the latex 'tummy'. The morcellation handles were attached to the wire ends. Force was applied to the handles in a sawing motion, however the force was applied laterally so the wires were always being pressed hard against the neck of the bag during morcellation. At the completion of morcellation the tissue was removed from the bag, and the bag was cleaned. The neck of the bag was visually inspected. The bag was filled with water to examine if any holes had formed (Figure 83).

There was no visible signs of cuts or tears in the bag. No holes were found when the bags were filled with water. It was concluded that the guard was not required to prevent the bag being cut.

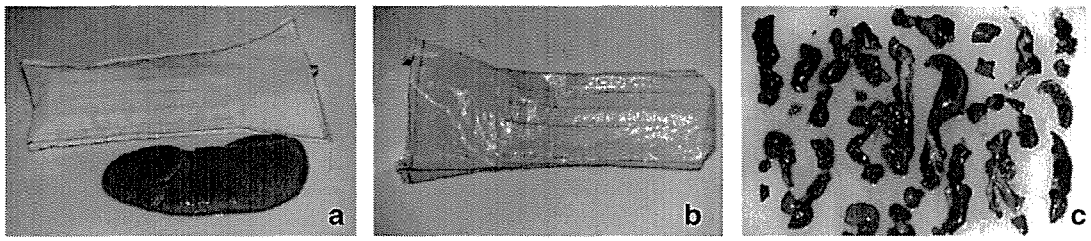


Figure 83 Confirming A Wire Guard is Not Required.

(a). Bag and Specimen Before Morcellation. (b). The Bag After the Experiment. (c). Resultant Tissue Fragments.

5.4.2 Design Development of the Insertion Handles

Establishing the Fundamental Characteristics of the Handle

A method for deploying the encapsulation bag into the patient had to be developed (Figure 84). A user approach for operating the insertion handle was developed. The bag would be injected into the patient in the same way fluids are injected using a syringe. By rolling up the bag and containing it inside a tube, the tube could be inserted down one of the cannula, and the bag could be injected into the patient. The mouth of the bag would remain fixed to the end of the plunger and thus the plunger would be used in conjunction with forceps to encapsulate an organ.

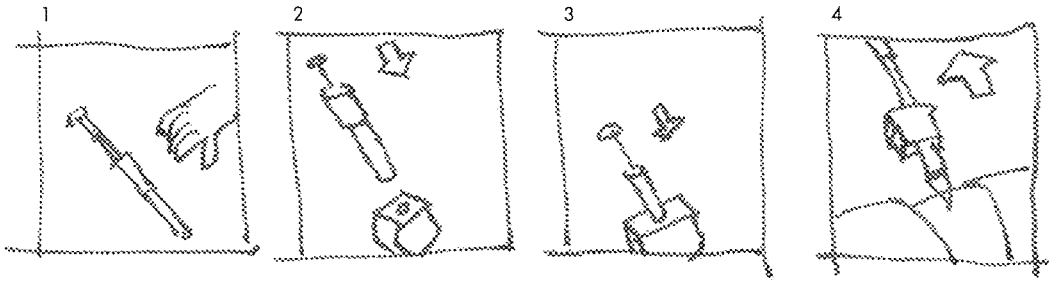


Figure 84 The User Concept for Operating the Insertion Handle.

1. Grasp from Package. 2. Insert Down Cannula. 3. Push Down Plunger and Inject Bag. 4. Following Capture of Organ, Simultaneously Pull up on Handle and Cannula to Exteriorise Bag from Patient.

The key elements required by the handle design were identified, (Figure 85). Using these four elements, the handle design was explored.

Some basic designs were drawn up, and quick foam models constructed to test the designs. Time was spent investigating how other designers had addressed the same requirements in related designs. Designs of pens and instruments which require rotation were of particular interest. Deliberately the handle forms were keep simple and without detail. Aesthetic detailing of the handles would occur later.

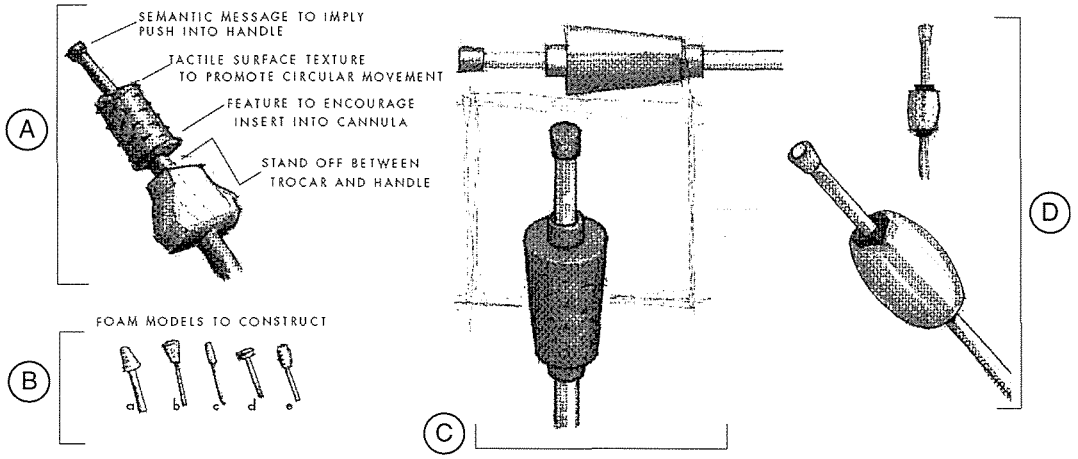


Figure 85 Exploration of the Handle Design.

(A) Outlining Required Features. (B) Basic Shapes for Foam Modelling. (C) Development Sketch of Foam Model "b". (D) Development Sketch of Foam Model "e".

Video Analysis of a Surgeon Operating

The foam models provided immediate tactile evaluation of the design approach, but there was a lack of understanding of how the surgeons would interact with such shapes. Observations conducted within the operating theatre to date had been useful for establishing a user concept, but they had not focused directly on the hand eye co-ordination and hand instrument interaction which occurs during surgery (Figure 86).

A video recording was taken of several operations. Particular attention was paid to the hand and eye movements of the surgeon. Variations in grip and hand position were noted. Specific parallels were sought between the insertion handle and how the surgeon used other instruments.

Some of the key observations were:

- The surgeon continually seeks to stabilise their hand while they are conducting any precise movements. This is done by using two hands or by stretching a finger out to rest against a cannula.
- The surgeon moves from the shoulder and elbow when changing the position of an instrument.

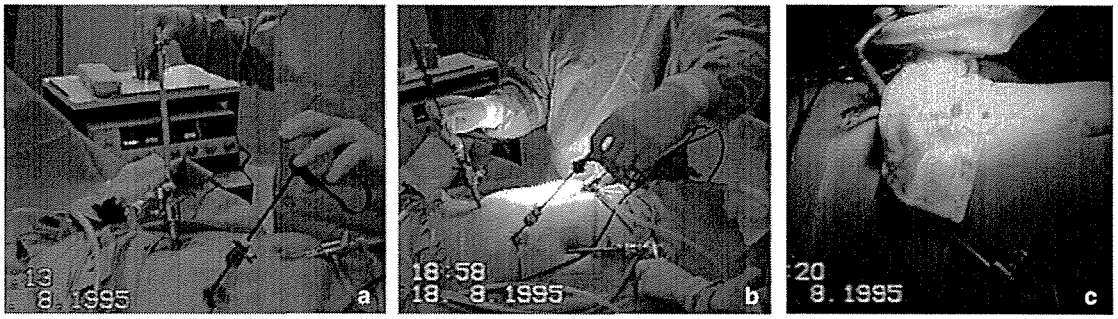


Figure 86 Parallel Operation Between Existing Instruments and the Insertion Handle.

(a). Insertion into Cannula. (b). Manoeuvring To Cauterised = Capturing and Organ. (c). Pulling out gall bladder = Exteriorising Bag.

- The surgeon keeps their wrist and hand still, only using their fingers for operating the controls of an instrument. For example squeezing the handle of a clip applier.
- The hands of the surgeon are generally kept in a relaxed, flat, downward orientation. A surgeon will totally ignore the manufacturers intended grip for an instrument if the grip forces the hands a grip other than this (Figure 87).

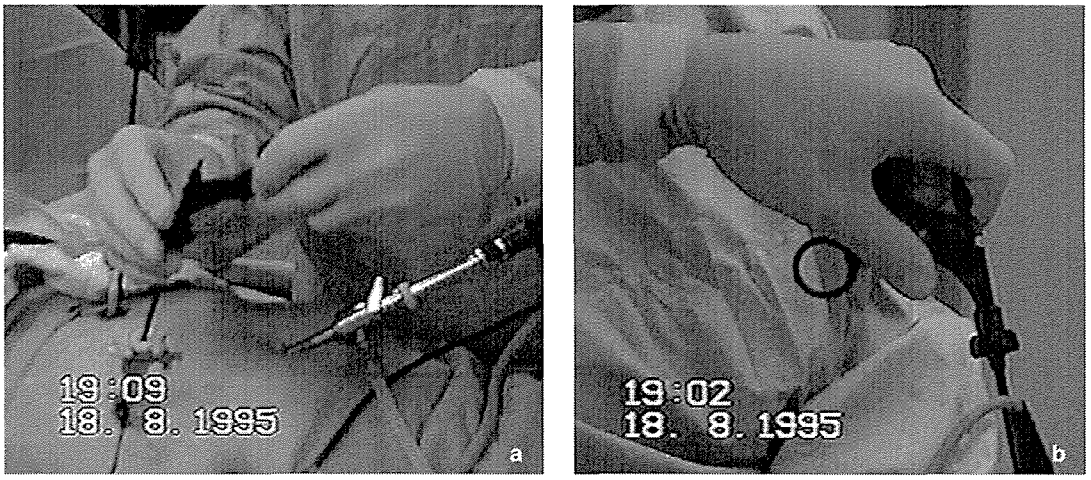


Figure 87 Video Analysis of Surgeon Operating.

(a). Two Handed use of One Instrument to Improve Hand Stability. (b). Surgeon Ignoring Manufacturers Intended Finger Grip.

Developing Three Design Concepts for Trialing

Based upon the observations derived from the video analysis of a surgeon operating in theatre, (Figures 86 and 87, p183), all designs aim to achieve the following:

- All handles are designed to be operated using the fingers while maintaining a stable hand and wrist position.

- The handles designs aim to be rotatable without detrimentally affecting the surgeons grip or control.

- The handles are of a size which will allow the surgeon to use both hands to maintain the stability of the implement.

Three basic shapes were conceived as being potentially suitable for the design:

- 1. A spherical shape similar to a joy stick (Figure 88).
- 2. a cylinder to be handled like a pencil (Figure 89, p186).
- 3. a cylinder with a thumb groove to be handled between the thumb and fingers (Figure 90, p187).

The forms of each concept were developed and dimensions specified for construction of three models suitable for user trialing.

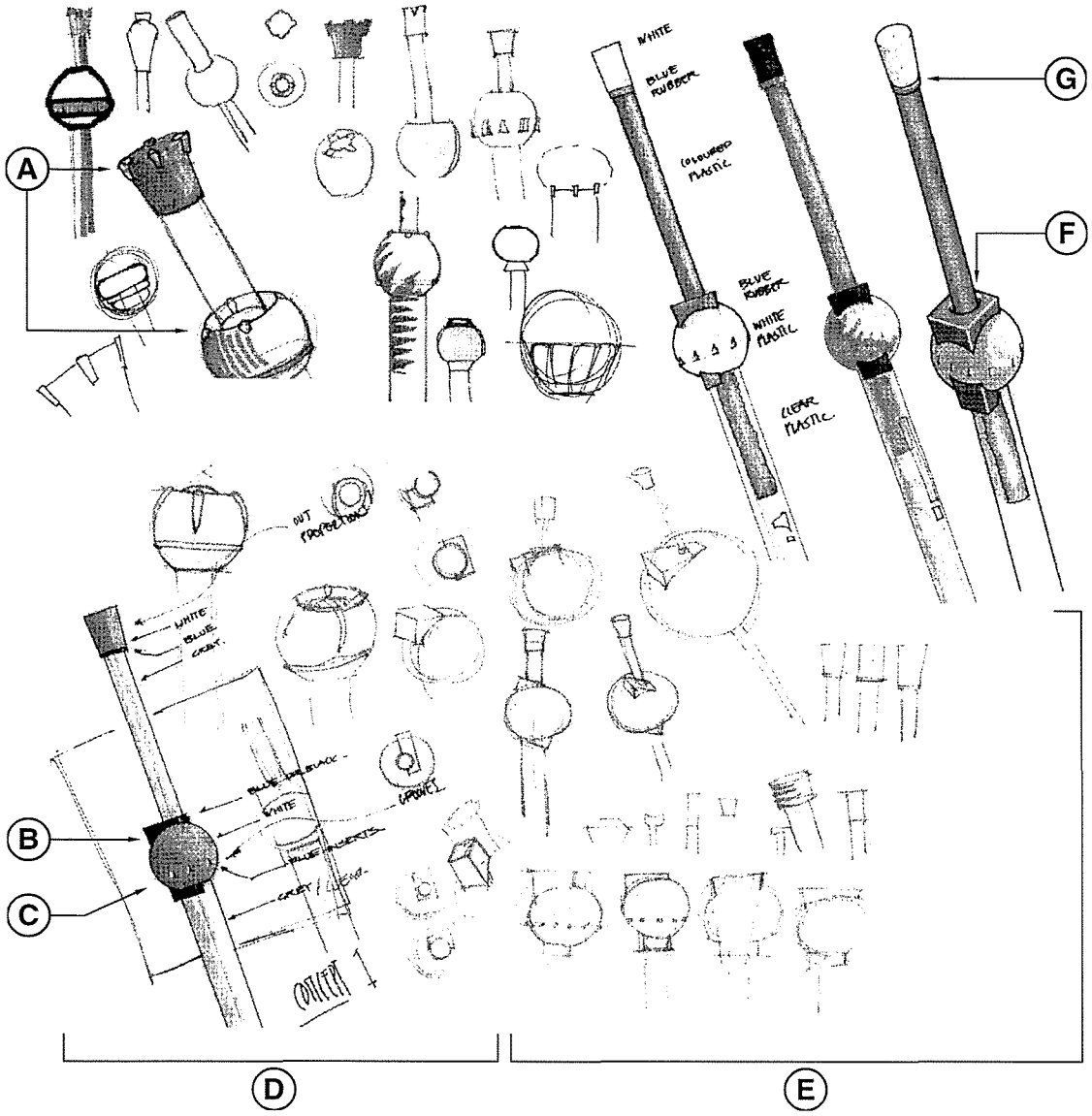


Figure 88 Development of Concept 1 (Spherical Shape) for Trialing.

Design features incorporated into the development of concept 1 (Figure 88):

A. Exploration detail to achieve semantic message of push plunger into handle. Ultimately decided to use a simple detail to prevent confusion (G).
B. An orientation notch to provide the surgeon with an external tactile and visual indicator of the rotational location of the encapsulation bag (fixed to the distal end of the implement).
C. Grip nodes to encourage the user to hold the spherical handle.
D. Accurate sketch used for construction of prototype.
E. Sketches exploring the proportional relationship between the orientation notch and the spherical handle.
F. Insertion plunger, when pressed fully in will finish flush with the top of the orientation notch.

G. Detailing to emphasise the physical link between the spherical handle and the plunger.

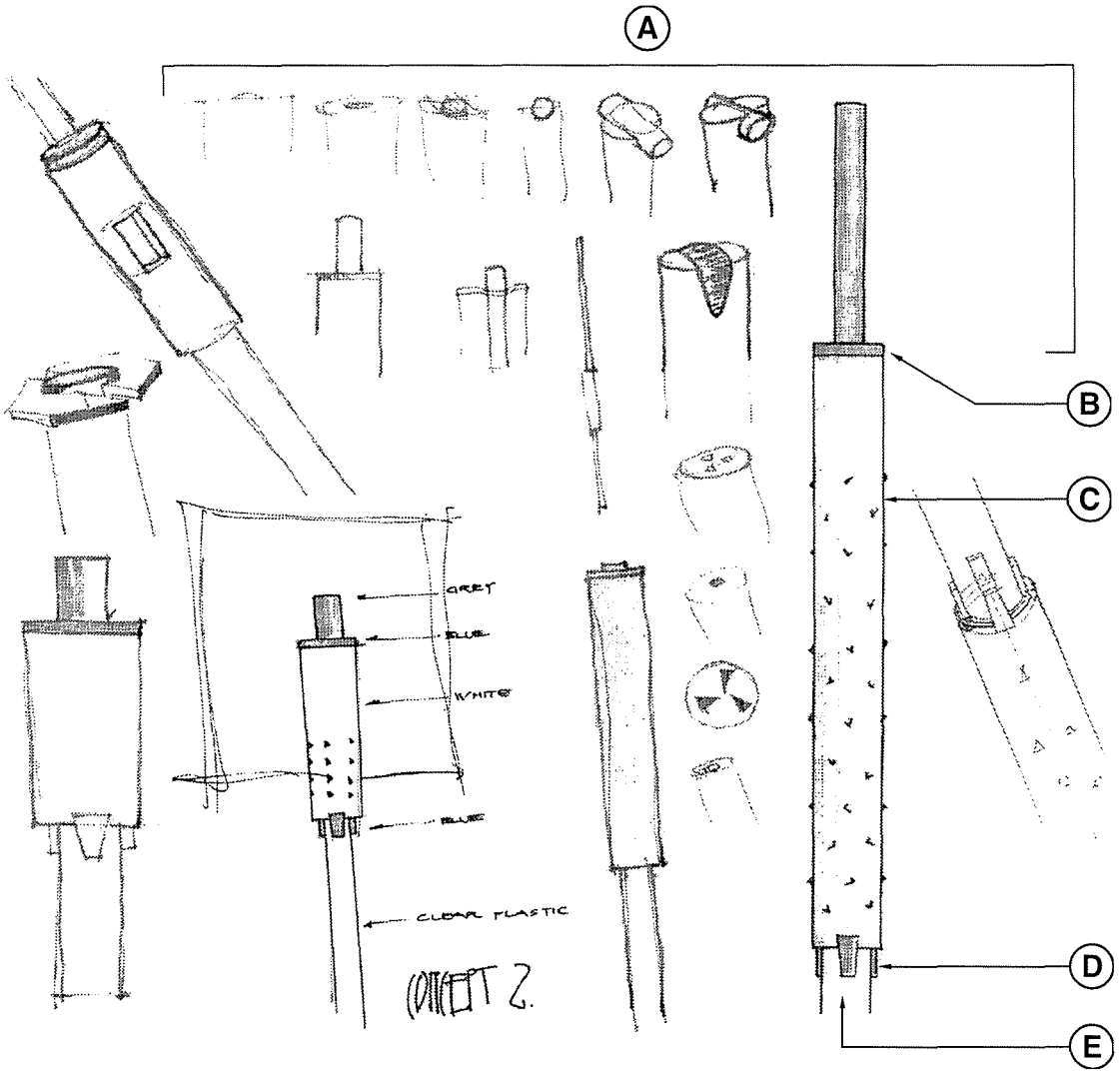


Figure 89 Development of Concept 2 (Cylindrical for Handling as a Pencil is Handled) for Trialing.

Design features incorporated into the development of concept 2 (Figure 89):

A. Exploration of handle and plunger detailing. Final shape deliberately kept simple to prevent user confusion.
B. Coloured ring to increase semantic significance of plunger insertion. Provides a visual stop point for the act of plunger depression.
C. Large grip area with distinctive grip nodes.
D. Inclusion of rubber "stand offs" to keep handle away from top surface of cannula into which it is inserted.
E. Accurate sketch used for prototype construction.

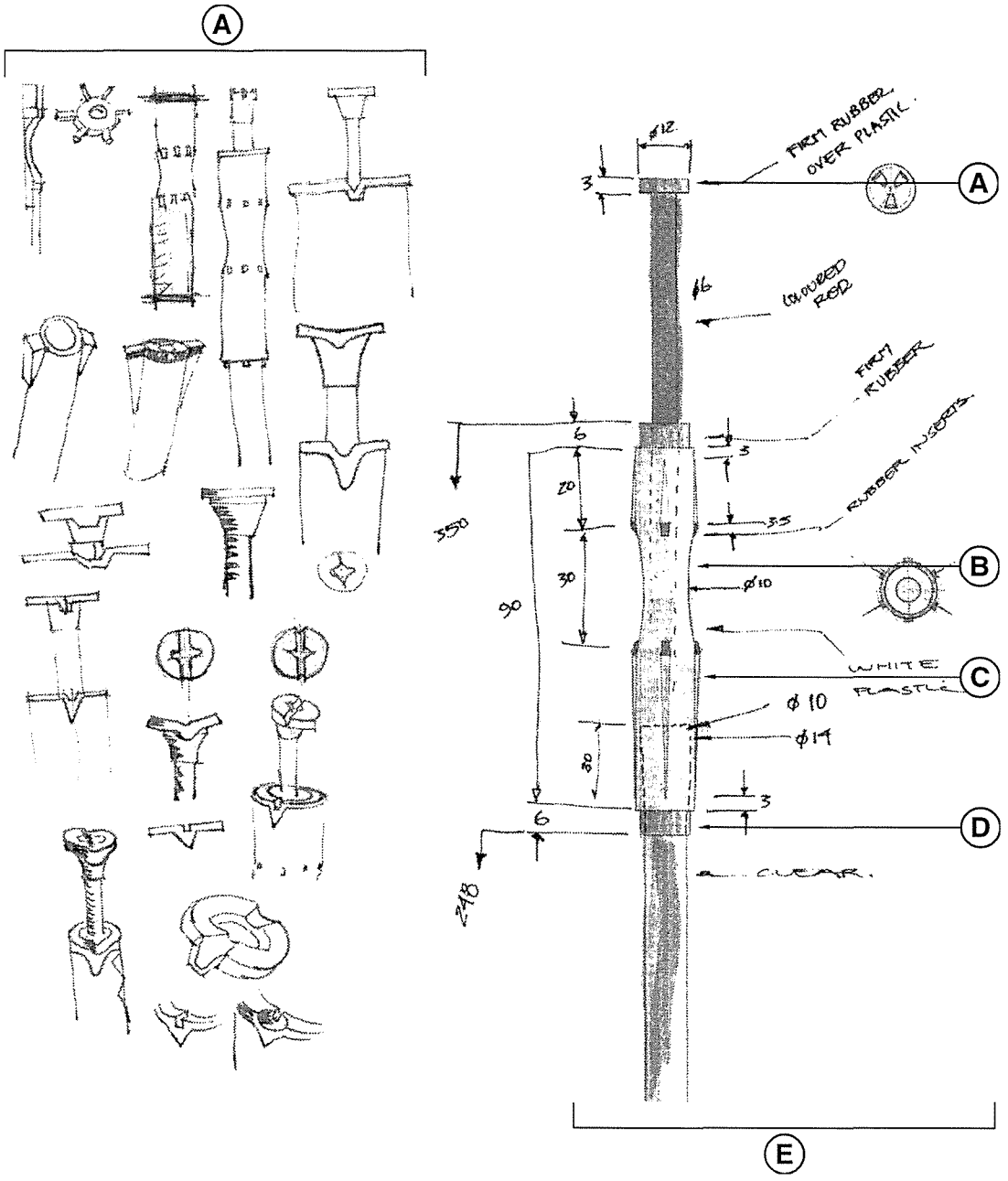


Figure 90 Development of Concept 3 (Cylindrical Shape with Thumb Groove) for Trialing.

Design features incorporated into the development of concept 3 (Figure 90):

A. Exploration of plunger shape / detail to promote insertion. Final shape selected kept simple, similar to the plunger on a syringe.
B. Smooth zone on upper half of handle to locate thumb and allow controlled rotation between the thumb and fingers.
C. Ribs to encourage the user to grip the handle.
D. Rubber "stand off" to maintain a gap between the insertion handle and the top surface of the cannula in which it is inserted.
E. Accurate sketch used for prototype construction.

5.4.3 Feedback from Industry on the Design

With the critical functional elements and components of the product designed, a provisional patent application was lodged. This enabled the marketing of the design to large medical companies to commence. An advertisement of the design to date was sent to two companies, Johnson & Johnson, and Smith & Nephew.

Using slides, and a model, the design was shown to the two companies. Both companies expressed interest but wished to see a video of the product in use. A video was produced of the design in use.

This video served two purposes, it aided commercialisation of the project, and secondly it provided a chance to conduct an evaluation of the design to date. The design used for testing consisted of the current encapsulation bag design, a simple cylindrical form for the insertion handle, and the aluminium morcellation handles constructed prior to the latex bag experiments. The evaluation would provide valuable feedback prior to exploring the design of the morcellation handles.

Trial 37 - Expert User Trial Analysis

An subject was selected to trial the device. The selected user had used the device in several of the previous prototype trials. He had become comfortable and confident with the device, and had a thorough understanding of the implement.

A mock patient was constructed using a latex abdominal wall as per previous trials. The experiment was set up to observe the expert user performing the following tasks:

- Introducing the insertion handle down a selected cannula.
- Pushing down the plunger on the insertion handle and injecting the organ entrapment bag into the patient.
- Using the entrapment bag in conjunction with forceps to capture an organ.
- Exteriorising the neck of the entrapment bag out the patient abdominal incision.
- Attaching the morcellation handles and slicing up the encapsulated specimen.
- Extraction of morcellated tissue strips using forceps.

- Removal of the empty encapsulation bag.

The entire trial was video recorded. Using the video recording, it was possible to conduct a detailed observation of the interaction between the expert user and the instrument.

Evaluation of the design revealed the following outcome:

-Two sliding surfaces of a handle cannot be placed side by side, or a surgical glove is likely to be pinched. When pushing in the plunger to insert the bag, the user's latex glove became pinched between the tube and the plunger (Figure 91).

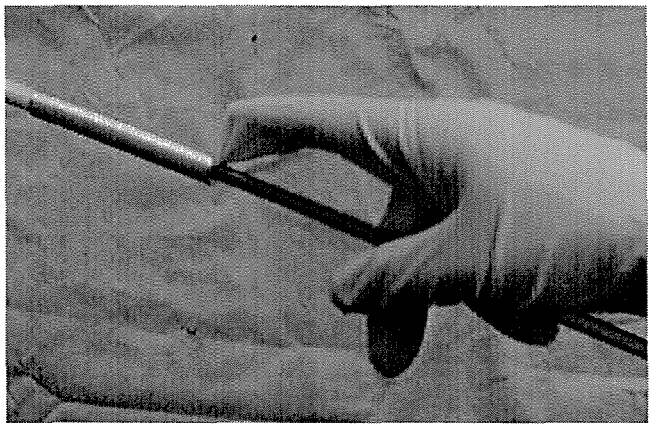


Figure 91 Pinching of Glove Between Two Surfaces.

- The insertion handle should have a ridged mouth edge, or be attached at an angle to the encapsulation sac to allow better manipulation when used in conjunction with forceps.
- The morcellation handles induced a turning force about the wrist. This was fatiguing and prevented accurate control of the handles.
- The assistant who held the bag during the morcellation process had difficulty sustaining a firm grip and upward force on the bag. The bag design must be amended to assist holding during morcellation.
- The force required to pull the cutting wires through the inner plastic skin of the bag and into the kidney was too excessive. The final design solution must require must less force.

Trial 38 - Novice User Trial Analysis

While all of the video equipment was still available, a second trial was conducted using two novice users. One user undertook the role of surgeon,

while the other the role of assistant. Mid way through the experiment they swapped roles. The purpose of the trial was examine the novice users ability to "automatically" use the device in the correct and intended manner.

All of the problems encountered with the expert user were also encountered by the novice users. In addition there were the following problems:

- Difficulty with capturing of the organ. The wires must be held securely against the side of the bag while the organ is being encapsulated. This is particularly critical around the mouth of the bag.

- The users were unsure of what part of the morcellation handle should be rotated to expose the hook. There was concern that the time to attach the wires to the morcellation handles was excessive (Figure 92).

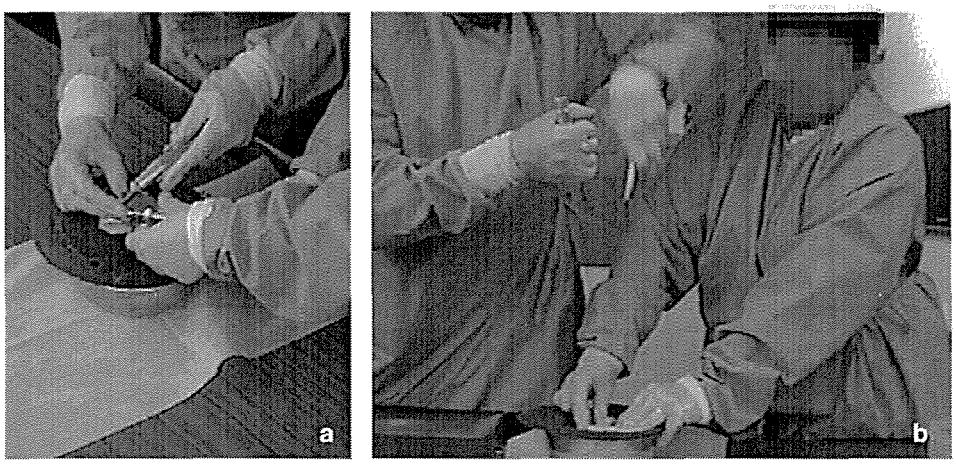


Figure 92 Novice User Trial Analysis.

(a). Difficulty When Attaching the Morcellation Handles. (b). Unclear Approach of Endpoint to Morcellation.

- When attaching the morcellation handles, the hook became entangled amongst the wires. A different system for attaching the wires is must be found.

- Both users were initially apprehensive about using the instrument and performing the morcellation action. After approximately 20 seconds of morcellation, the apprehension disappeared.

- The end of the morcellation process was unclear and as a result there is the risk of flicking out tissue fragments as the final cut is made. A

method needed to be developed for advising the surgeon that morcellation is almost complete (Figure 92, p190).

5.4.4 Refinement of the Design

Using information gathered from the user trial the design was refined. The bag was improved, three design concepts for the morcellation handles were established, and the remaining two insertion handle design concepts were constructed.

Refining the Encapsulation Bag Design

Design exploration into ways of improving the handling of the bag during morcellation was conducted. A modified bag profile was proposed which would allow the mouth of the bag to be folded back over itself to form a handle. The issue of an unclear endpoint to morcellation was addressed by attaching markers onto the wires so that the quantity of tissue remaining to be cut could be evaluated.

Developing Three Design Concepts for the Morcellation Handles

The specific requirements of the handles were defined. Three concepts were generated using sketches and observation of pulling actions in everyday objects (Figure 93). The three concepts all incorporated a rapid wire attachment and release system. This system was discarded for the simple crimp and socket system used to attach cables to equipment, (for example the attaching of brake cables on bicycles).

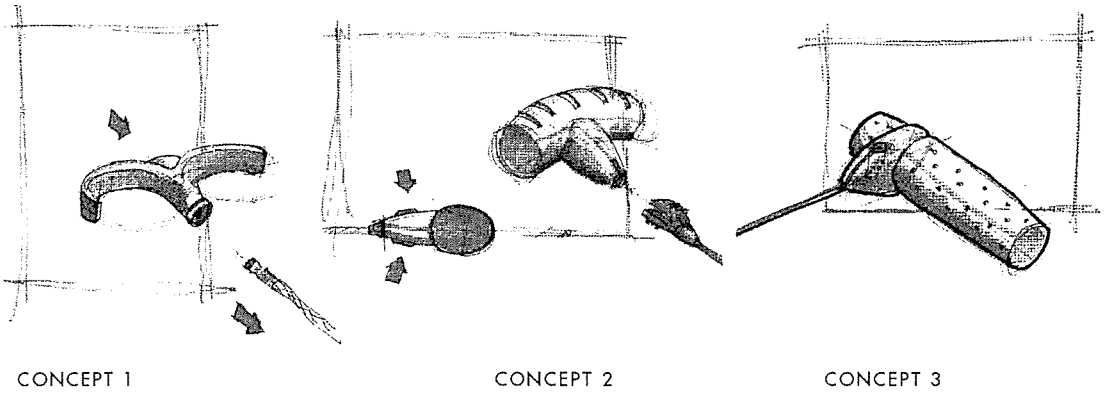


Figure 93 Three Design Concepts for the Morcellation Handles.

Concept 1 is designed to be supported by the fingers, but with an open hand. Concept 2 is also supported by the fingers but with a closed hand . Concept 3 explores using a closed hand about a full length handle.

The three designs were dimensioned and constructed for user trialing (Figure 94).

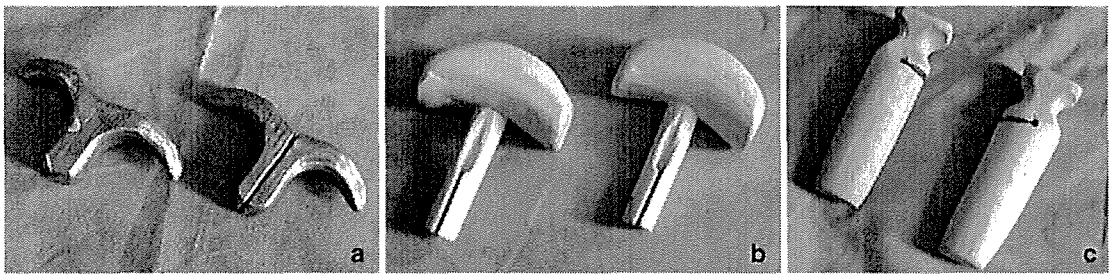


Figure 94 The Three Models Prepared for Testing.

5.4.5 Novice User Trial Analysis - Non Medical User

An experiment to evaluate the proposed design was developed. The experiment trialed the three insertion handle concepts and the three morcellation handle concepts.

Trials 39-40 - Trial Analysis of the Insertion Handles

A Cannula was inserted into the latex 'tummy'. Each of the three insertion handles were inserted down the cannula, and then the plunger was depressed, representing the deployment of the encapsulation bag into the patient. Following insertion , the user was asked to manoeuvre the handle and point to four marker points. By moving the handle to these points the user had to perform: a rotational movement, a further insertion movement, a retraction movement and several lateral displacement movements. The entire process of insertion and manoeuvring was repeated three times.

Summary of experiment results:

- Concept 1 (the spherical design) was not well received (Figure 95). The user complained of a lack of control. The user often totally ignored the handle and grasped the main tube between thumb and fingers. The user did not push down on the top of the plunger with a finger but gripped the side of the plunger and fed it into the handle.

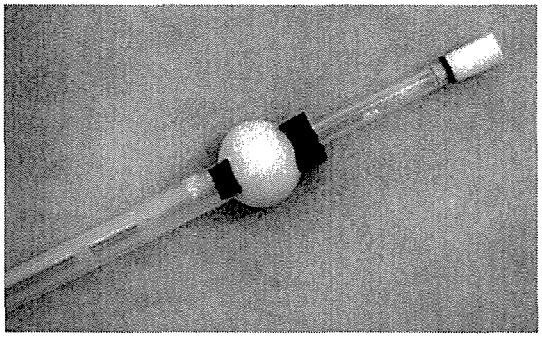


Figure 95 Insertion Handle Concept 1.

- Concept 2 (the plain cylindrical shape) received little comment (Figure 96). The simple shape produced no confusion. As with concept 1, the plunger was operated by gripping the side and feeding it into the handle.

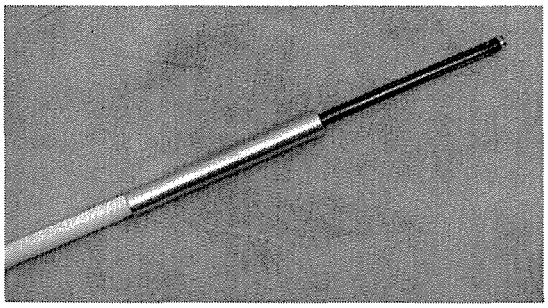


Figure 96 Insertion Handle Concept 2.

- Concept 3 (the cylindrical shape with the thumb groove) received positive comments (Figure 97). Initially the plunger was operated as the previous two concepts, but for the second and third insertions the plunger was depressed as a syringe is depressed. The grip was not used correctly at all. The user grasped the top of the device and turned it like a knob.

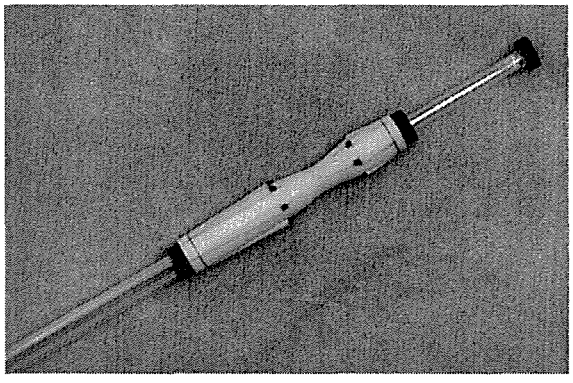


Figure 97 Insertion Handle Concept 3.

In conclusion of the analysis it became apparent that the forms for concept 1 and 3 were too complex and the user had difficulty interpreting the correct way of using the implement. The semantic messages of the handles were far to vague and misdirected to work effectively. On this basis, later design development of the insertion handle tended toward a passive cylindrical shape, similar to that of Concept 2.

Trial 41 - Trial Analysis of the Morcellating Handles

To trial the morcellation handles, the user was asked to attach a group of crimped wire ends to the handles. The assembly was then draped over a piece of timber and the user gripped the handles to perform a sawing action on the timber. Timber was used because it eliminated the need to build many test bags and purchase kidneys. In addition to the three design concepts being trialed, the original handles constructed for the latex bag trials were also analysed. The user was asked to morcellate in steady firm strokes for 30 seconds and then with rapid strokes for 15 seconds.

The significant results were:

- Concept 1 (Figure 94a p192, Open hand design) was handled in the desired manner. The user kept their hand relaxed, and only tensed their fingers under the handle (Figure 98). The centre piece of the design was considered too large and uncomfortable. The pointed shape of the handle ends was too sharp. Attaching the wire crimps was described as easy, except the insertion groove should be widened.

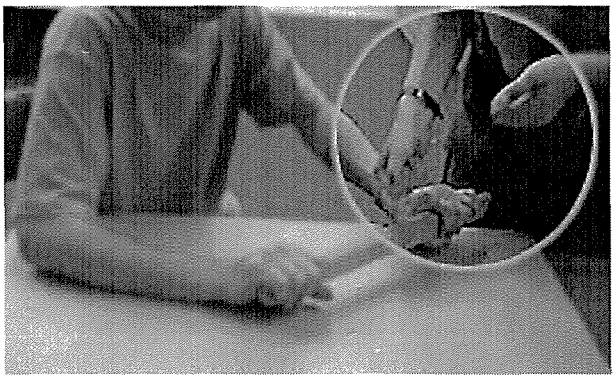


Figure 98 Morcellation Handle Concept 1 In Use.

- Concept 2 (Figure 94b p192, Closed fist design) was described as providing a good balance between control and force (Figure 99). The

size of the handle was too large and several times the user had to relax and re-grip the handle. The user also complained that their fingers became wedged against the central shaft. Attaching the wire crimps appeared difficult and fiddly.

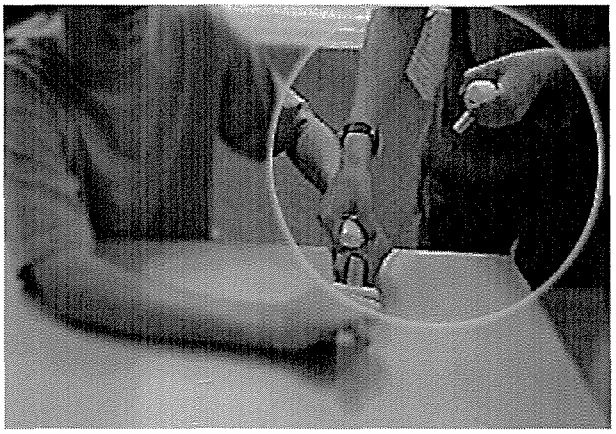


Figure 99 Morcellation Handle Concept 2 In Use.

- Concept 3 (Figure 94c p192, Closed hand and full length) was described as comfortable but had no feeling of control (Figure 100). All force came from the arms and shoulder with no control by the fingers at all. The handles could generate huge amounts of force. The wire crimps were attached easily.

Figure 100 Morcellation Handle Concept 3 In Use.

- The original handles constructed for the latex bag trials were trialed last (Figure 101). The handles were criticised for being tiring and causing wrist pain. There was a lack of apparent control as the wires were held in an almost remote location. It was difficult to attach the wire loops with out pinching the surgical gloves.

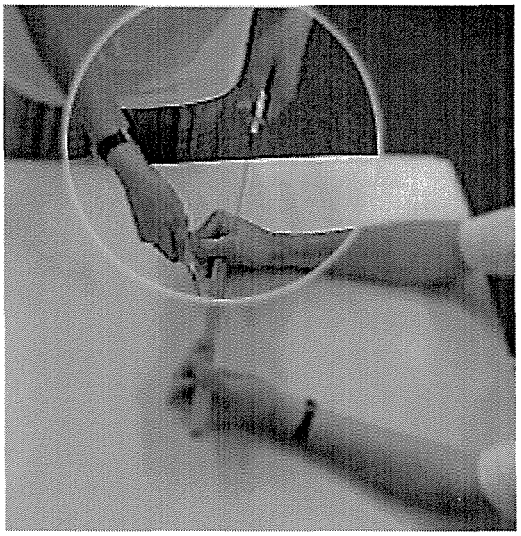


Figure 101 Morcellation Handle Original Design In Use.

The conclusion of this analysis highlighted that concept 1 had no significant problem that could not be corrected with refinement of the design.

5.4.6 Novice User Trial Analysis - Surgeon

A highly skilled endoscopic surgeon was chosen for the final trial user analysis. The surgeon represents a novice user of the instrument, but an expert user in the field of minimal access surgery. The experiments were conducted in the endoscopic training unit at the Royal Brisbane Hospital. The experiment tested the complete device in use. The three insertion concepts were trialed, and the three morcellation handle designs were trialed.

Trial 42 - Analysis of the Insertion Handles

A surgical trainer was set up in representation of the patient. A number of cannula were inserted into the unit. Each of the three insertion handles were inserted down the cannula , and then the plunger was depressed, signifying the deployment of the encapsulation bag into the patient (Figure 102). The process was repeated three times with each handle.

Figure 102 Using One of the Three Insertion Handle Concepts.

The important results of the experiment:

- Concept 1 (Figure 95, p193) The surgeon ignored the handle completely and only grasped the plunger or main tube. The design was unsatisfactory.

- Concept 2 (Figure 96, p193) was favoured as a simple tool designed to do the job at hand. The surgeon gripped the design two ways, as a pencil and flat between the thumb and fingers.

- Concept 3 (Figure 97, p193) was also unsatisfactory. The surgeon gripped the lower portion of the handle and did not use the thumb groove at all.

- In all three designs the plunger was depressed by feeding it down between the thumb and fingers. Only for the last few centimetres of insertion was the plunger depressed using a finger.

In conclusion of this trial, concepts 1 and 3 seem inappropriate and ill-favoured for the task. The final design should be more subtle and strive less to control the surgeons hands movements but instead support the variety of basic grip techniques. The plunger should be designed to be fed into the handle rather than being depressed by a single finger.

Trial 43 - Encapsulating an Organ

The cylindrical handle was inserted and attached to an encapsulation sac. Using an endoscope and television monitor for visualisation, a kidney was manoeuvred into the encapsulation bag. The cylindrical handle was selected

because there had been a strong reaction against insertion handle designs concepts 1 and 3.

The main observations and conclusions from the test:

- The mouth of the bag was only reinforced and made rigid using masking tape. The final design should be substantially more firm.
- Methods employed by the surgeon to encapsulate the organ will vary from physician to physician. The design should be suitable to support a variety of griping instruments and manoeuvring techniques.
- The surgeon looks at the monitor while encapsulating the organ. The instrument is controlled totally by feel. It is important that the instrument have some tactile markings for the surgeon to be able feel physical movements of the handle in relation to the changes of the visual image on the monitor. By connecting the visual image with the tactile feedback from the handle movements, the surgeon is able to establish a frame of reference, and better control the operation.

Trial 44-46 - Analysis of the Morcellation Handles

The trial of the morcellation handles was conducted on the surgical trainer. A kidney was placed inside an encapsulation bag, the neck of the bag was exteriorised out one of the trocar incisions, the morcellation handles were attached to the wire crimps, and the specimen was morcellated.

The most surprising, and somewhat disturbing observation was the aggression and tremendous force which the surgeon applied while conducting morcellation. When queried about the large applied force the physician replied "We'll, that's the idea isn't it, to get the thing out?"

Comments made regarding the bag design were:

- Not to make the wires too short, as longer wires enable a longer sawing stroke, and also help made attaching to the crimps easier.
- The folded down lip on the front of the bag significantly improved the ability to grasp and stabilise the bag during morcellation.

Conclusions on each of the morcellation handles:

- Concept 1 (Figure 94a, p192) was regarded as the most appropriate size and shape. The surgeon held the handles exactly as desired.

Comments were made regarding the rounding, and smoothing of the shape.

- Concept 2 (Figure 94b, p192) was described as being too large in the hand. The user appeared to be unable to find a comfortable grip. With a relaxed hand the handle did not feel secure, while a closed hand grip did not provide enough control.

- Concept 3 (Figure 94c, p192) was disliked. The surgeon complained of no feeling of control.

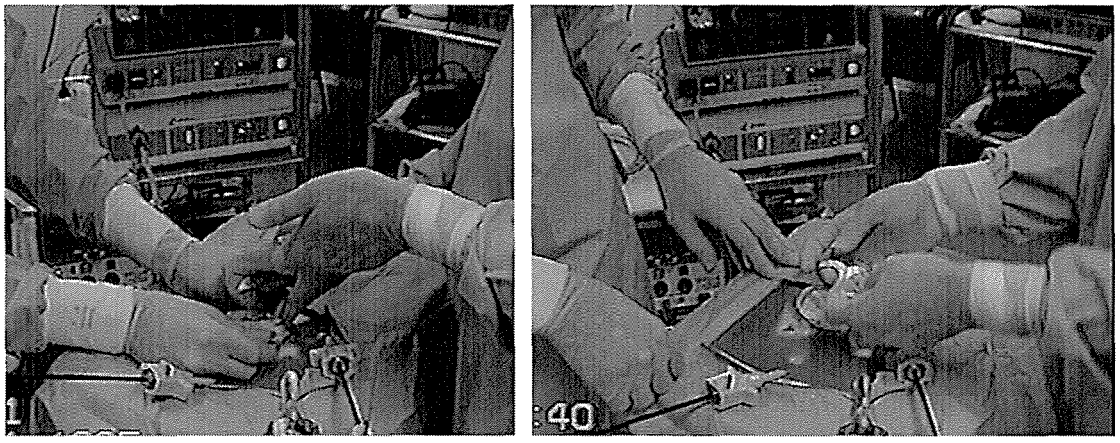


Figure 103 Morcellation Handle Concept 1 In Use.

In correlation with the results from the previous user analysis (Trial 41, p194), concept 1 came out as significantly more favourable, and thus was selected as the direction for the design to proceed. The following points reinforce the decision:

- There was no confusion on how to attach the cutting wires to the morcellation handle.

- The users immediately knew how to grip and hold the morcellation handles.

- The handle was held in the user's fingers, but they did not close their fist around the device (Figure 103). Instead the users kept their hand open, allowing their wrist to remain static. The elbow and shoulder provided gross movement, while fine movements were facilitated by their fingers. This technique of instrument control is in direct

accordance with the techniques observed during the "Video Analysis of a Surgeon Operating" (Figure 86 and 87, p183).

- The size and shape were well received. The form needs rounding and smoothing to improve grip comfort.

5.4.7 Final Design Development

Using the results and recommendations from the user analysis experiments, the final design development occurred. Manufacturing and material constraints were considered. Each of the remaining design criteria were addressed. The Provision for company logos and product graphics was explored. Using sketches and renderings, the final design emerged and the design freeze took place.

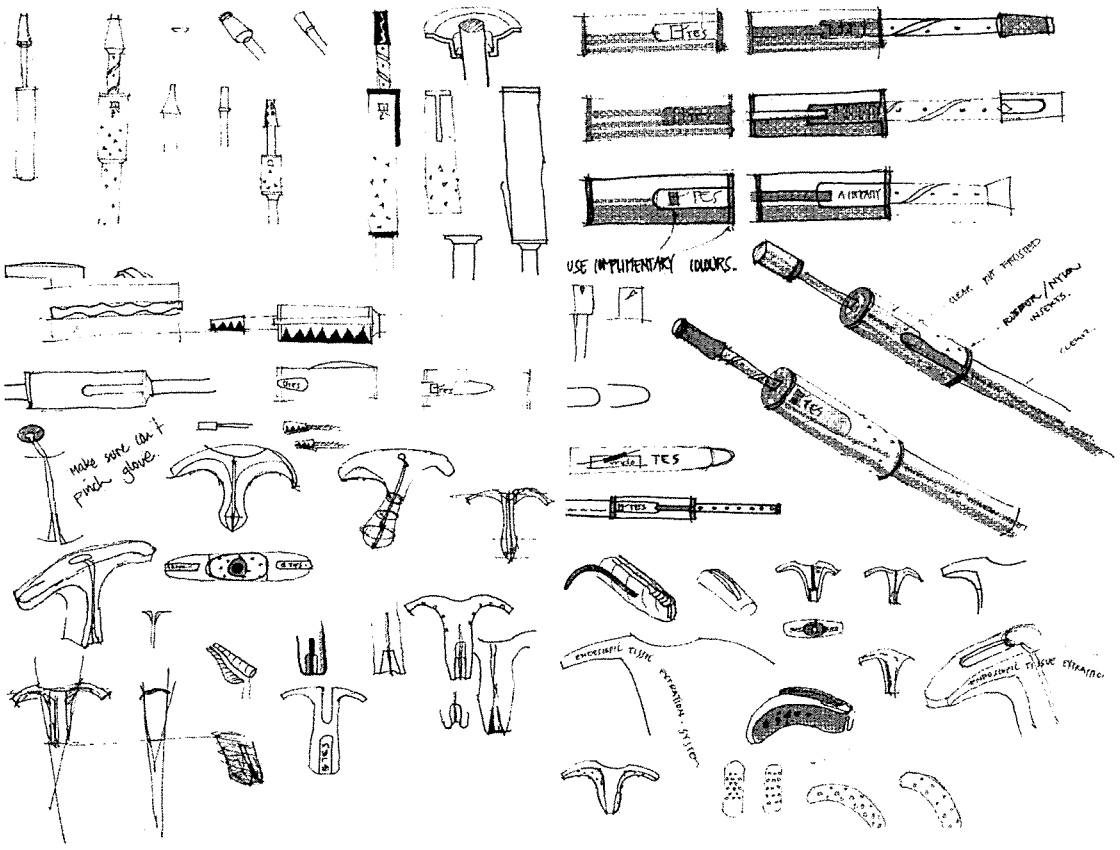


Figure 104 Final Design Development Sketches.

In addition to a disposable design, a re-useable product was also conceived. This was achieved by modifying the materials and adapting the numerous

aspects of the design for reuse. The bag and delivery tube remained as disposable items.

Trial 47 - Trial on a Human Fibroid

In the months leading up to the design freeze, a request was made to obtain a human fibroid to trial the design with. A fibroid did not become available until several weeks after the design freeze had occurred. The aim of the experiment was to test how the device would perform on an extremely fibrous and tough specimen. The device had been working successfully on kidneys which contain a mixture of fibrous and soft tissues, but no testing had been performed on a completely fibrous mass.

The experiment was set up as per the previous trials using the latex 'abdomen' and the stainless steel bowl to represent the patient.

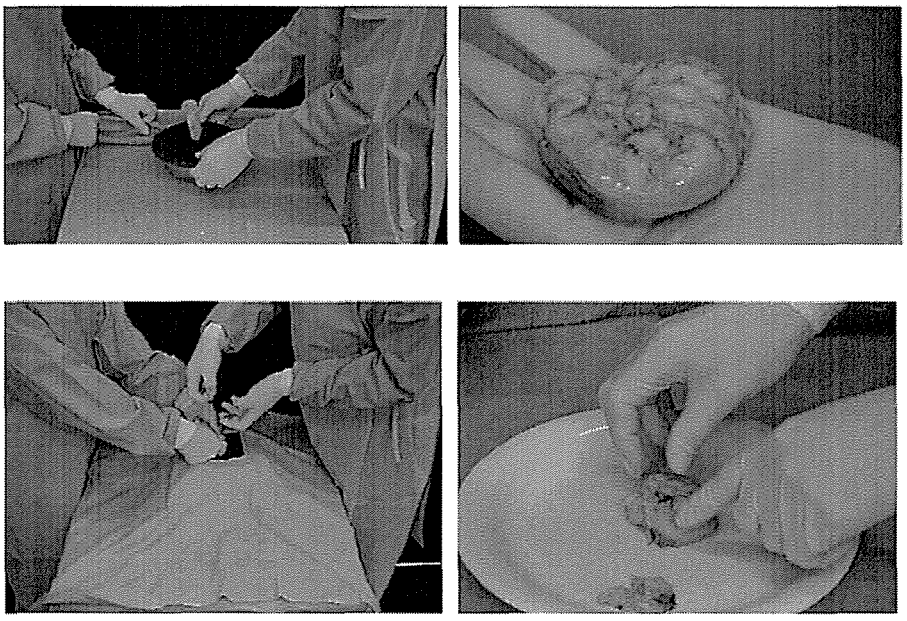


Figure 105 Trial 47 - Trial on a Human Fibroid.

Three attempts were made to morcellate the specimen. Each attempt failed. The wires did not cut sufficiently into the fibroid, instead they partially sliced into the specimen before slipping around the tissue. This has been attributed to the limited cutting ability of the stainless steel wire used for the prototype. To solve the problem a cutting wire with a more aggressive finish was investigated. Diamond coated wires were explored but unfortunately nothing sufficiently flexible could be found in the limited time available. As there did not remain sufficient time to further explore the cutting wire specifications (and also as the design freeze had taken place several weeks ago), it was

decided to leave the sourcing or development of the wire until after the thesis was submitted, and attention was refocussed on commercialising the project.

It is also noted that if a more aggressive cutting wire is found, it will be necessary to re-assess whether the protective guard described in Section 5.4.1, Trials 35 - 36, p180, is required.

5.4.8 The Development of a Package Design Concept

The main focus of this project was to develop a tissue and organ extraction device. For this reason the packaging has had some initial consideration, however the packaging design remains in an initial concept stage and has not been subjected to any user testing or detailed development.

Design of the packaging commenced once the dimensions of the organ and tissue extractor had been finalised. A literature review was conducted into packaging design, focusing specifically on medical packaging design. A large amount of information was available on the effects of sterilisation on packages, and different material strengths of packages however, virtually no information had been published on the handling requirements of packages containing sterile surgical instruments.

A study of existing product packages was conducted. Packages for staplers, trocars, clip appliers, forceps, and many other disposable package designs were examined. These were used as case studies showing variations in materials, production techniques, form configurations, and container graphics.

A list of design criteria was established. The fully completed list is contained in Section 4.7, p134. The list covered such issues as:

- Functional Requirements
- Handling and User Needs
- Storage and Distribution Criteria
- Production Constraints
- Desired Package Semantics and Aesthetics
- Required Package Graphics.

Once the criteria had been established, the design was explored (Figure 106). The non specific company name of "ACME Medical Incorporated" was chosen for representation on the packaging. A non specific company name

was selected because while pursuing the commercialisation of the project, the design will be shown to a variety of medical companies, and it would be unwise to have any particular corporations name associated with the design.

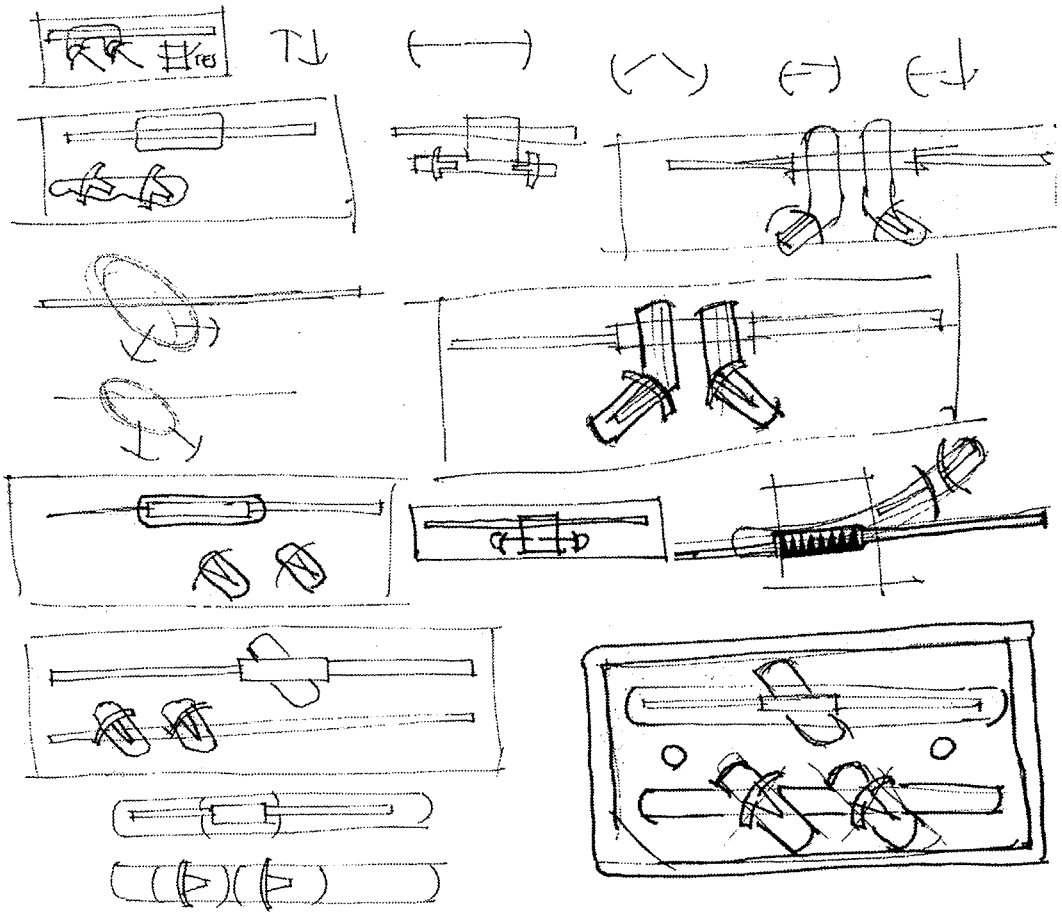


Figure 106 Designing the Packaging.

The rectangular shape repeated throughout the sketches represents the PETE tray into which the Morcellation Handles and the Insertion Handles are located.

After exploration of the design using sketching and rendering, scale drawings were produced and a an initial design concept was established. It is presented in Chapter 6 along with the final proposed design.

5.4.9 Review of Methodology Used for Stage 4 - Solution

Stage 4 was the most successful stage of the project. Experiment trials were conducted under better control and observed with more effective recording methods. More testing on a wider group of users would have been advantageous, however time restrictions did not allow this.

The weakest aspect of the stage was undoubtedly a lack of co-ordination between commercialisation and research activities. Following the development of the successful latex bag solution, a provisional patent application was drawn up and filed. The patenting and commercialisation activities were very time consuming. This should not have occurred until much later in the design process, when the final design freeze took place. By postponing commercialisation activities, important research would not have been delayed. Additionally the twelve month provisional patent time period would have been available for the sole activity of 'selling' the design, rather than trying to 'sell' and further develop the design simultaneously.

5.5 Summary

Chapter 4 lists design criteria relevant to the design of instruments to extract large tissue specimens and organs in endoscopy. At its beginning, the list provided a base upon which the design process (Chapter 5) could commence.

A four stage research and design process was employed to develop a new product for the extraction of large tissue specimens and organs at endoscopy. Chapter 5 has documented this process. The final proposed design is presented and discussed in Chapter 6.

CHAPTER 6

A Final Design

"You must begin with an ideal and end with an ideal." (Sir Frederick Banting)

The initial starting point of a design project can often be difficult to pin point on a time scale. Does a project begin with the first inkling of a thought or does it commence with the first drawing? Similarly the completion point of a project can be equally difficult to specify. To prevent projects from continuing on for excessively extended periods of time, budget and time deadlines are established. In addition to time and budget deadlines, there are specific design aims and objectives to fulfil. The endpoint of a design project, also described as the design freeze, is defined by the point at which the time and budget deadline are reached, in combination with the satisfactory addressing of the necessary aims and objectives of the project.

When assessing and evaluating a completed design it is important to examine the justification and reasoning behind the final solution. A justification provides record of why particular decisions have been made, and insight into the influential factors contributing to a design outcome.

This chapter presents and justifies the final design solution. The justification is based upon the design criteria checklist established in Chapter 4, and the results of the trials documented in Chapter 5.

This chapter is divided into three sections

- The Concept: describing the fundamental workings and operation of the design (Section 6.1).
- Operation of the Instrument: details how the instrument is intended to be used (Section 6.2).
- Specification: provides technical information and dimensions pertaining to the final product Section 6.3).

The chapter closes with a brief summary.

In addition to the design of the tissue and organ extraction instrument, a graphic logo, and a packaging concept for the product have also been described. The design has been labelled "endoTES" derived from: **endo**scopic **T**issue **E**xtraction **S**ystem. Four items make up endoTES: An Insertion Handle, An Encapsulation Bag, and two Morcellation Handles. Each of these items is displayed in Figure 107.

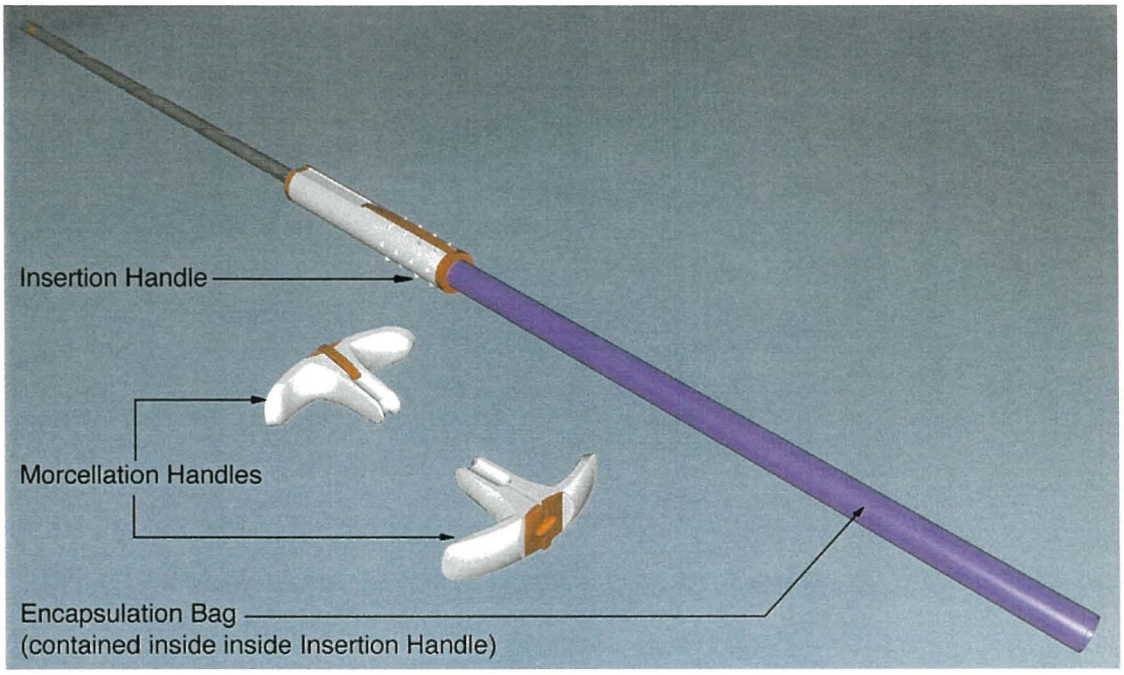


Figure 107 The Final Proposed Design.

6.1 The Concept

The final design concept aims to achieve a simple task:

> Take a large tissue specimen the size of an adults clenched fist, and remove it from a patient through a 10mm incision without contacting the sides of the incision, and without spilling a cell from the specimen. Additionally the resultant tissue pieces have to be the size of an adults Finger.

The results of Trials 18, p169, and 27-36, p179, demonstrate the final design achieving this simply and efficiently. The design concept (Figure 108) operates in the following sequence of steps:

1. An impermeable bag with fine wires attached to its inside surface is inserted into the patient.
2. The bag is used to encapsulate the specimen for removal.
3. Once encapsulated, the neck of the bag is exteriorised.
4. Upward force is applied to the fine wires in a sawing motion and the specimen is sliced into strips.
5. Once slicing is complete, forceps are employed to retrieve the tissue strips from within the bag.

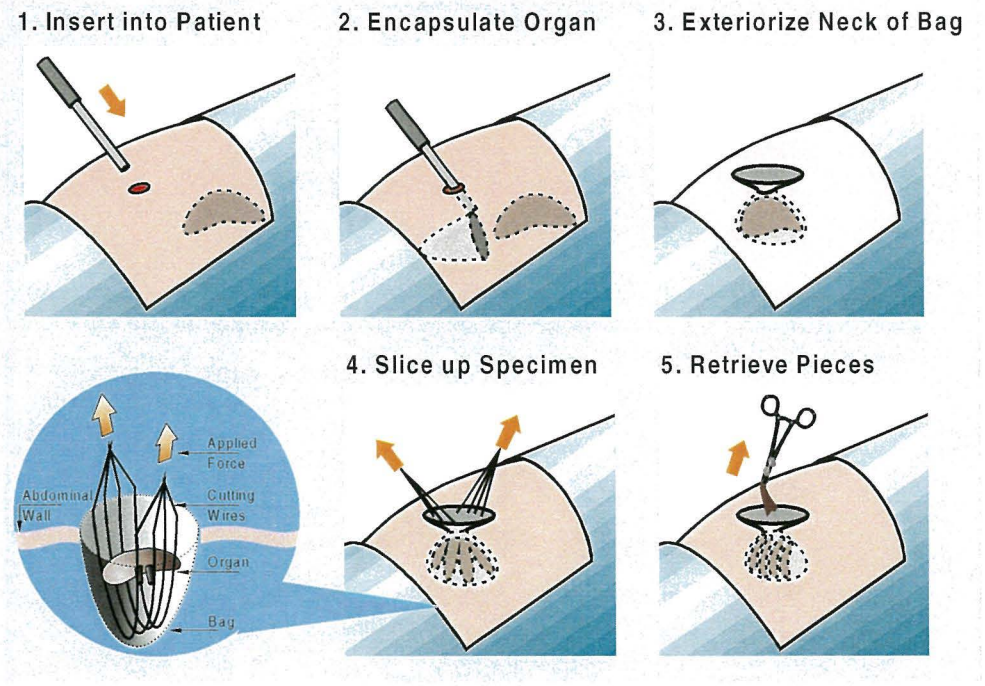


Figure 108 The Final Design Concept.

Page 209 missing

6.2.1 Step 1 - Opening of the Package

The overall process of opening the product package and delivering endoTES to the sterile field conforms with current sterile handling practices.

The scout nurse retrieves the white cardboard external packaging box (Figure 48, pp 134) from theatre storage. The ends of the external packaging box are only folded closed, not glued, thus the box is easily opened. The sealed plastic internal package (Figure 48, p134) is retrieved from within the external box (Figure 109a).

The scout nurse grasps the underside of the internal package and peals off the package's polymer seal using the corner pulling tab. The corner pulling tab facilitates controlled, and stable handling of the package (Figure 109b).

Using only one hand, the sterile nurse reaches into the internal package sterile zone, and lifts out the sterile instrument tray containing endoTES. The sterile plastic tray (containing endoTES) is placed onto the general operative instrument trays, along side all of the other sterile instruments being used throughout the operation (Figure 109). During the operation, the sterile nurse retrieves the required endoTES product component (insertion handle, or morcellation handles,) from the plastic tray, and passes them to the physician.

There are four advantages of containing endoTES within a totally sterile tray:

- The tray can be placed directly into the operative area, thus keeping all of the components of endoTES together and grouped.
- The entire endoTES instrument tray can be handled with two hands without contamination of sterility.
- Retrieval of endoTES components is made easier, and more controlled as the sterile nurse can use both hands. This reduces the chance of dropping an instrument as it is introduced into the sterile field.
- The ability to handle the tray with two hands allows for more secure containment of endoTES, and thus less chance of accidental release of the product during transit.

The above described features, are all aimed to prevent contamination of the sterile field through handling errors.

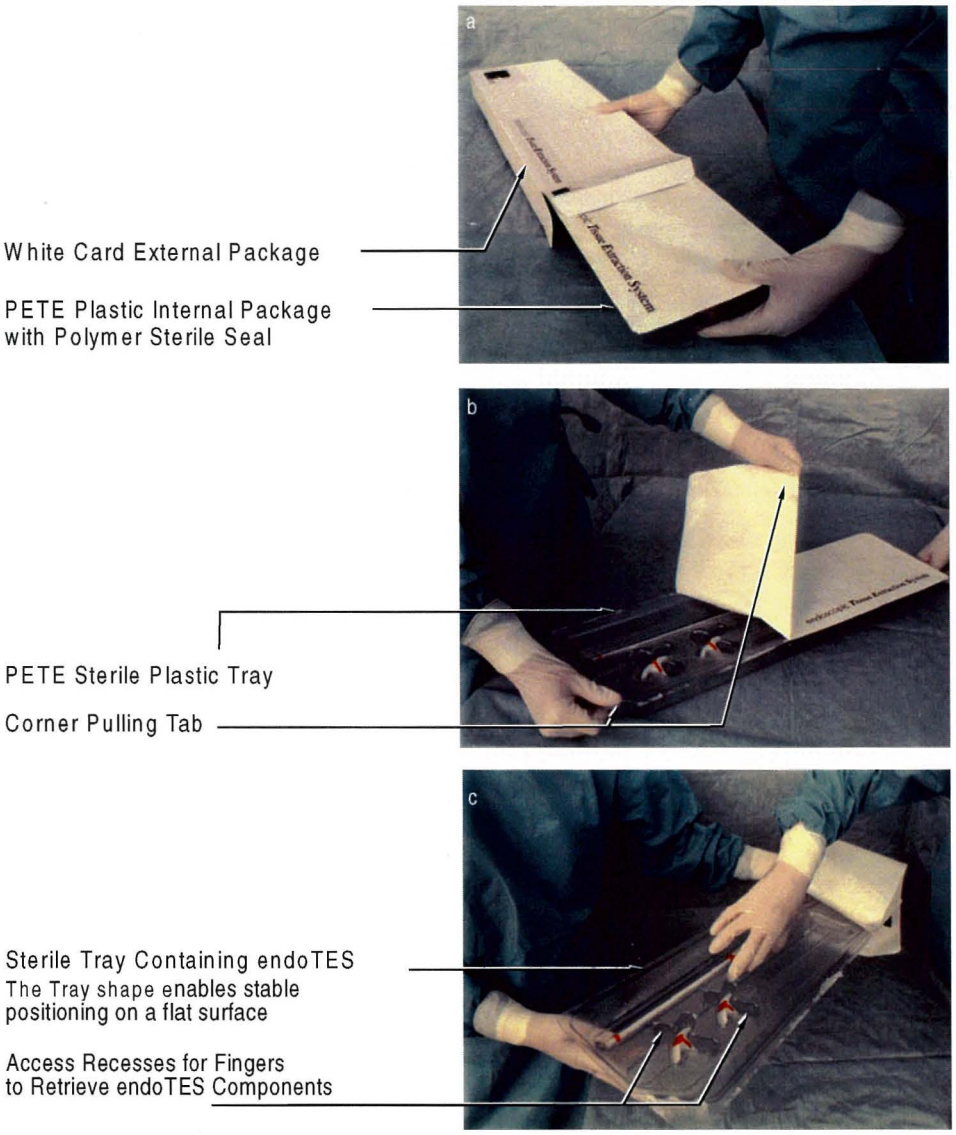


Figure 109 Opening the Package

(a). Removing the Internal Package from the External Package. (b). Opening the Internal Package. (c). Removing the Sterile Tray from within the Internal Package.

6.2.2 Insertion

The second step involved in using endoTES is to insert the device into the patient.

The insertion handle and plunger are grasped from the package and inserted down one of the established 10mm (or larger) surgical ports (Figure 110a). EndoTES can be used in conjunction with any 10mm or greater surgical port, therefore making the device totally suitable for thoracic and paediatric applications. The length of the insertion handle provides ample griping space

for the sterile nurse to pass the device to the surgeon, without risk of mishandling.

The surgeon grasps the insertion handle and pushes down the plunger in a steady screwing action (Figure 110b). The screwing action is very clearly implied by the visible screw thread moulded into the plunger. The front tube of the insertion handle is constructed of a transparent material, providing the surgeon with visual feedback of the plunger, injecting the encapsulation bag into the patient. As the plunger reaches the end of travel, a tactile 'click' is felt, signifying the end of movement.

The plunger is pushed entirely into the handle. Simultaneously the encapsulation sac will be ejected from the end of the insertion handle and into the patients body (Figure 110c). Once inserted, the bag remains fixed to the end of the plunger and insertion handle.

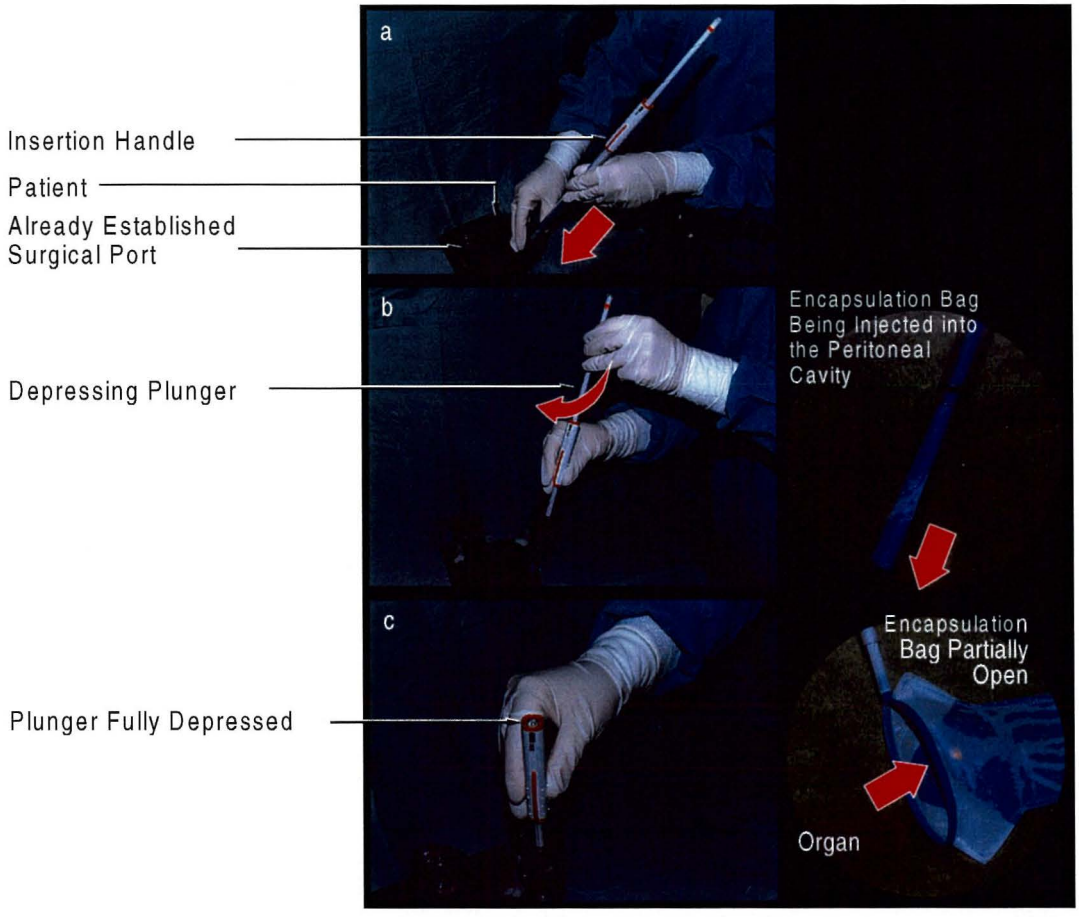


Figure 110 Insertion into The Patient.

(a). Introducing the Insertion Handle into the Patient. (b). Injection of the Encapsulation Bag. (c). The Encapsulation Bag Fully Inserted and Open Inside the Patient's Peritoneal Cavity.

The plunger has been designed to be gripped on the side and fed into the insertion handle. This complies with the observations made during Trials 39-40, pp 192, and Trial 42, p196, in which all of the observed users, gripped the side of the plunger to depress it in to the insertion handle.

To prevent the possibility of the surgeon's glove being pinched between the insertion handle and the plunger (while the plunger is being depressed), there is a recess around the top of the insertion handle (Figure 111b).

The round forms of the insertion handle and the plunger provide a substantial grip area for a firm controlled grip. The grip area on the insertion handle is highlighted by the small tactile nodes around the bottom of the handle (Figure 111c). Additionally the screwing action reduces the forces required to eject the encapsulation bag from within the insertion handle.

The visually distinctive screw thread on the plunger very clearly implies the required operation of the plunger. Additionally the bright orange rubber ring about the top of the plunger visually connects with the orange ring around the top of the insertion handle, therefore implying insertion. Furthermore, the rubber ring about the top of the plunger contains directional 'pointers' also implying insertion (Figure 111a).

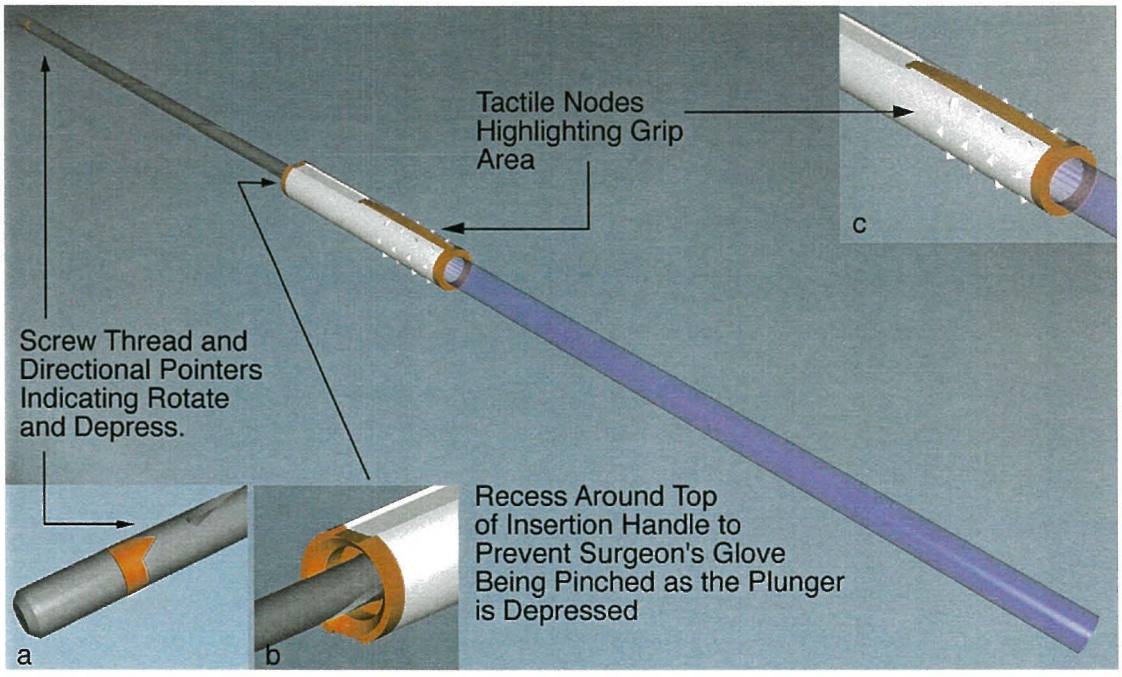


Figure 111 Insertion Handle Design Feature.

(a). Rubber Ring with Directional Pointers. (b). Recess to Prevent Glove Pinching. (c). Distinctive Grip Nodes.

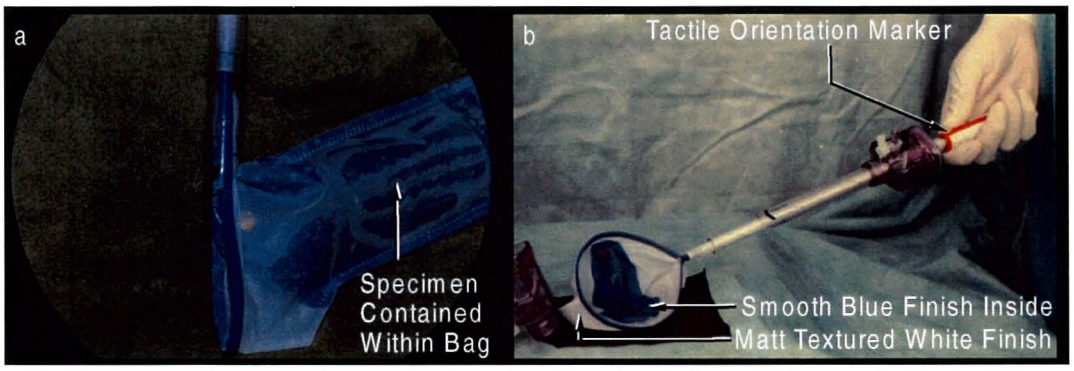
6.2.3 Encapsulation

The third step involved in using endoTES is encapsulation of the specimen for extraction. Prior to the insertion handle being introduced into the patient, the surgeon will have mobilised the specimen being extracted. This is achieved using the typical surgical techniques described in Chapter 2.

Once inserted, the mouth of the bag will spring open (Figure 110c, pp 212) The surgeon may be required to use atraumatic forceps (or lavage handle) to facilitate complete opening of the encapsulation bag, as it will have been rolled up inside the insertion handle since assembly at manufacture. Forceps are introduced through a second (already established) port to grasp the specimen and manoeuvre it inside the bag. The round form of the insertion handle allows the surgeon to use his fingers to perform precise and highly controlled manoeuvres, while maintaining a stable wrist position, as was found in 5.4.2 (Video Analysis of a Surgeon, p182). To assist with capture of the organ, the mouth of the bag is reinforced with a plastic rib.

Once the specimen is encapsulated, the insertion handle is drawn up, pulling the mouth of the bag inside the surgical port (Figure 112a). The surgical port is removed from the patient, thus exteriorising the neck of the encapsulation bag. The mouth of the bag is pulled from the surgical port (Figure 112b). This step, effectively seals and separates the encapsulated specimen from the patient. Having the specimen for extraction totally sealed from the patient prevents any possible spread of diseased cells to healthy organs, and thus makes endoTES suitable for use with cancerous tissues.

The mouth of the encapsulation bag is highlighted using a vibrant blue colour for improved visibility and definition of depth. Blue being selected because it contrasts against yellow fatty tissue, and the white encapsulation bag. Further more, to help differentiation between the inside and the outside of the encapsulation bag, the external surface of the bag is a matt, textured, white finish, while the inside is a smooth light blue finish. On the insertion handle, a rubber rib provides a tactile orientation marker, for the surgeon to utilise in linking his physical actions, with the visual image on the operative monitor (Figure 112). Each of the above described features responds directly to the observations and conclusions of Trial 43, p197.



Drawing Mouth of Bag
Up into Surgicalport

Exteriorisation of the Mouth
of the Encapsulation Bag

Figure 112 Encapsulation

(a). Encapsulation Bag, with Contained Specimen Being Drawn Inside Surgical Port. (b). Exteriorisation of the Neck of the Bag.

6.2.4 Morcellation

Contained between a thin plastic film and the inner surface of the encapsulation bag are fine cutting wires. Two crimps hold the ends of the wires in opposing groups (Figure 113a). The crimps and wires are contained under a thin plastic film to prevent them from blocking the bag opening and interfering with the encapsulation of the organ, as was found in Trial 38, p189. With the neck of the bag exteriorised, and turned down, the surgeon pushes the circular wire crimps through the perforated thin plastic film (Figure 113a).

The morcellation handles are taken from the sterile instrument tray and attached to the wire crimps. This is achieved by advancing the base of the morcellation handle, into the wire stands approximately 10mm below the wire crimp. The concave shape of the morcellation handle, funnels the wires into the thin groove, running the full length of handle (Figure 113b). The circular wire crimp is then pulled over the top of the morcellation handle, and released into the corresponding circular cavity (Figure 113b). As the wire crimp is slid into position, a positive tactile click signifies to the surgeon that the crimp is secure.

To improve the user task of locating the cutting wires onto the morcellation handles, a concave shape was added to the base of the handles. This addressed the issues regarding difficulties of attaching the cutting wires to the morcellation handle raised in Trials 38 p189, Trial 41 p194, and Trials 44 - 46 p198.

Addressing an additional issue of Trials 41 p194, and Trials 44 - 46 p198, the tactile click felt by the surgeon, acts as a retainer to prevent the wires from unintentionally releasing, from the morcellation handle during the procedure.

Similarly to the insertion handle, there is a recess around the top of the morcellation handles to prevent the surgeons glove from being pinched as the circular wire crimps are clicked in place (Figure 113b).

There exists a directional pointer on the morcellation handle and a corresponding indent on the wire crimp. Therefore a visual link is established between the two items, thus implying to the surgeon to insert the crimp into the receptive handle (Figure 113b, p166). This visual detail, in combination with a side rib, match the directional pointer, and orientation rib of the insertion handle (Figure 111c, p213).

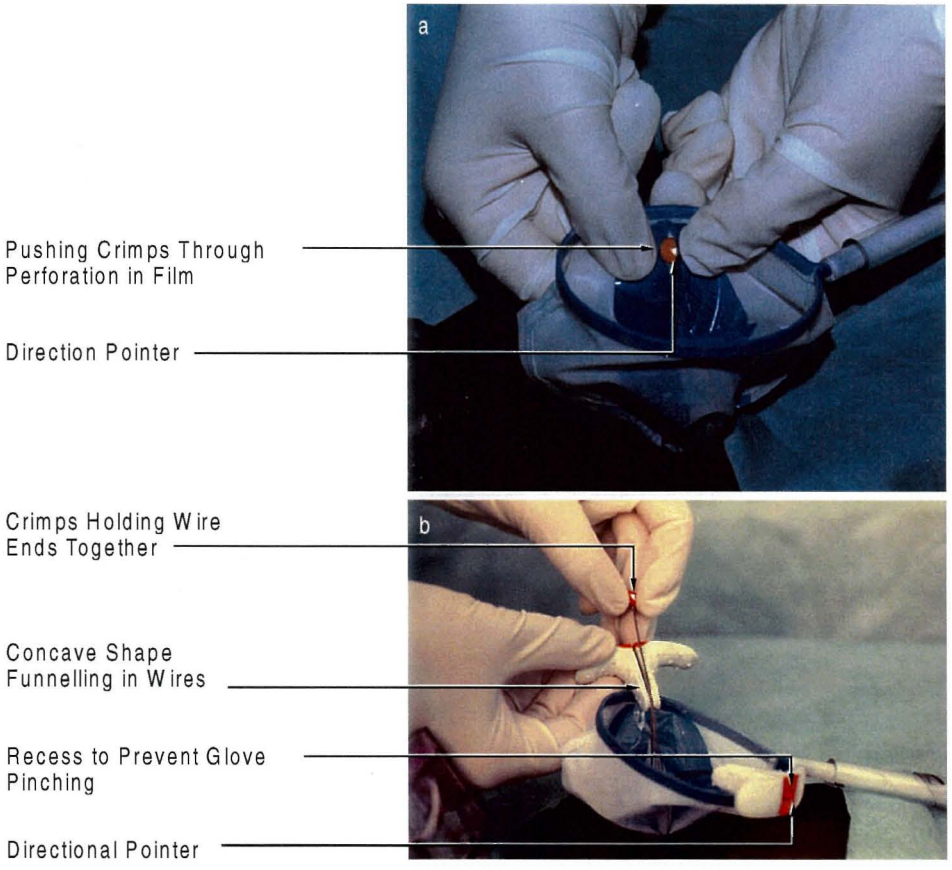


Figure 113 Attaching the Morcellation Handles

(a). Accessing Wire Crimps. (b). Attaching the Morcellation Handles.

The assisting physician grips the down turned mouth of the encapsulation bag and applies a steady upward force. The shape of the encapsulation bag allows the physician to locate their fingers in a handle cavity created by

folding the bag back over itself. The fold is created by the profile of the bag, where the diameter of the mouth is slightly smaller than the bag diameter 20mm below the opening (Figure 112a, p215). This design feature was utilised in response to bag handling issues raised in Trials 37 p188, and 38 p189.

With one hand grasping the morcellation handle and the other hand supporting the facia around the incision, the surgeon performs the first cut. The first handle is released and the process is repeated with the second handle. This pulls the wires through the thin plastic film on the inner sides of the bag, and into the contained organ (Figure 114a).

The surgeon then grasps both handles and using a firm, steady sawing motion, slices through the specimen (Figure 114b). During the entire encapsulation, morcellation, and extraction process, the surgeon is able to monitor the procedure, inside the patient via the endoscope, and externally by direct visualisation of the operative site.

The morcellation handles have a smooth rounded underside, with small grip nodes, however there is a crisp edge where the top surface meets the side faces. This shape make the handle comfortable to hold with the fingers in an open grip (Figure 114), but uncomfortable to hold if the hand is clenched tight. This encourages the physician to maintain a steady, relaxed, wrist position, with the arm and elbow providing the sawing motion, allowing the fingers to perform any precise, controlled movements. This gripping technique conforms to the observations and recommendations made in Section 5.4.2 (Video Analysis of a Surgeon Operating, p182), and the results of Trials 44 - 46, pp 198-200.

During sawing, the markers on the cutting wires are monitored to gauge how much tissue remains to be cut (Figure 114c). As the last tissue mass is sliced through, the applied cutting force is reduced, until such time as the wires are totally released. These markers address the issue of an unclear approach of the endpoint of morcellation, raised in Trial 38, p189.

The grip nodes on the morcellation handle clearly signify where the handle is to be grasped. The flat, rubber area on top of the handle provides a resting location for the thumb during the morcellation process (Figure 114). This is important because it prevents the arousal of feelings of non-confidence, when there is no comfortable grip provision for all of the users fingers (or thumb).

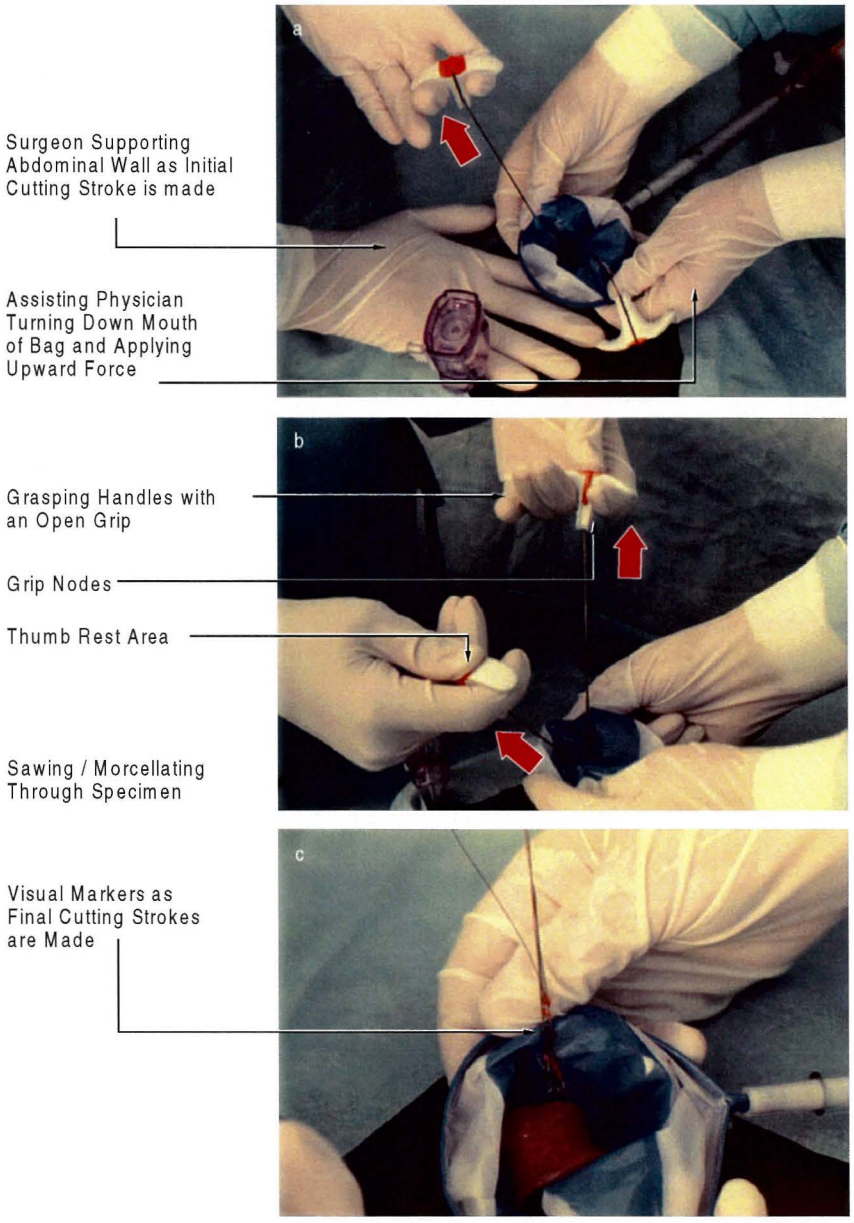


Figure 114 Morcellation

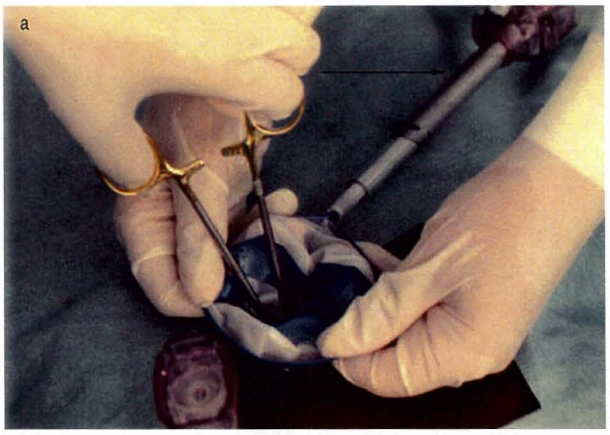
(a). The First Cutting Strokes. (b). Slicing Through the Specimen. (c). Visual Markers on the Cutting Wires.

The predominant forces resulting from the cutting action, focus on the organ being sliced up. Theses forces are inwards towards the specimen and away from the external surfaces of the bag. At the incision site, where the neck of the bag exists the patient, there are frictional forces between the cutting wires and the bag. However as was proven in Trials 35 - 36 (Confirming a Wire Guard is Not Required, p180) , there is no damage to the encapsulation bag from the morcellation process. Additionally, as the cutting wires move through the incision site in a predominantly vertical motion, there is absolute minimal additional trauma to the incision site.

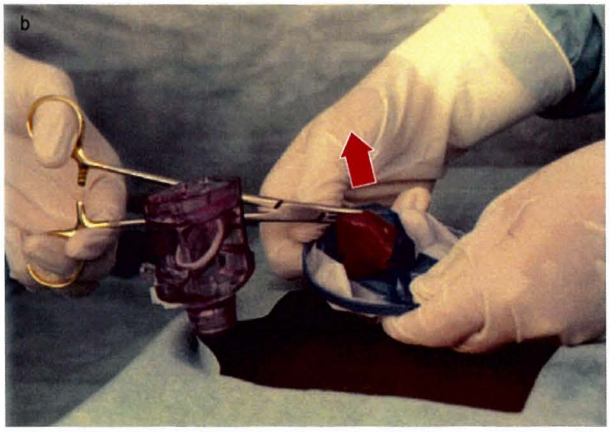
6.2.5 Extraction

The assisting physician maintains their upward grasp on the bag while the surgeon employs blunt nosed, atraumatic forceps to retrieve the tissue slices from within the bag (figure 115a, Figure 115b). The slices are placed into a specimen dish. Once most of the tissue has been removed, the bag is drawn out the incision (Figure 115c), any remaining tissue will be drawn out with the bag, and emptied onto the sample dish.

Grasping Morcellated Tissue Using atraumatic Forceps



Removing Tissue from Bag



Removing Bag from the Patient

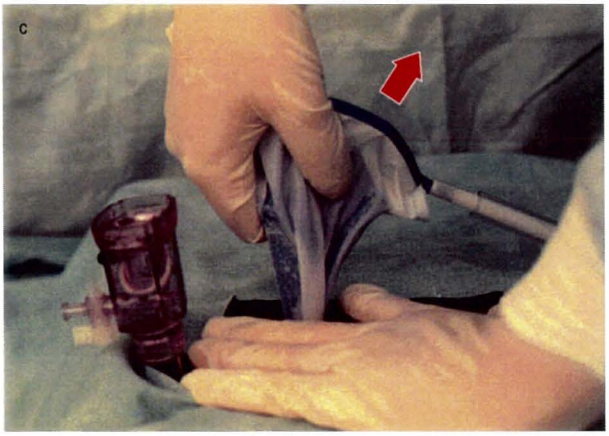


Figure 115 Extraction

(a). Grasping the Tissue Slices. (b). Retrieving Tissue Slices. (c). Removing the Empty Bag.

The resultant tissue fragments are delivered to pathology as a series of strips (approximately 10mm x 10mm) which can be sorted to provide a neat series of cross sections through the organ. The cutting planes are neat, there is minimal permanent cell deformation, and the vascular structures remain in tact and easily identifiable. If desired, the surgeon can mark specific sites on the organ with clips prior to morcellation. The clips will not be dislodged during morcellation and remain in place for the pathologist. An outcome of high quality resultant tissue fragments, has been observed in Trials 8, 18, 19, 27 - 38, and 44 - 46.

During the entire morcellation and extraction process, the specimen is always totally sealed off from the patient, thereby preventing the spread of diseased cells about the incision sites, or peritoneal cavity. With the knowledge that no diseased tissue will contaminate surrounding tissue, endoTES can be used on malignant, or benign cancerous tissues.

EndoTES is inserted down a sealed trocar and during extraction, the bag presses and seals around the incision site. As a result of these two properties, there is negligible loss of pneumoperitoneum from this technique. The importance of maintaining sufficient pneumoperitoneum, is that the surgeon never loses visual feedback (and thus control) of the internal aspects of the operation.

The entire encapsulation, morcellation and extraction process is performed through an already established 10mm trocar incision. There are no additional incisions, and there is no enlargement of existing incisions.

6.2.6 Disposal

The morcellation handles and cutting wire are disposed of immediately after the slicing has been completed. Disposal of the insertion handle and encapsulation bag will vary depending whether a disposable surgical port or reusable cannula has been used. If a disposable Surgiport port has been used then all three items are disposed of immediately following the emptying of the bag onto the sample dish. If a reusable cannula has been used, then following the emptying of the bag, the sac is drawn through the cannula and disposed of. The cannula is withdrawn from the sterile environment and sent for cleaning. It is contaminated with diseased cells and is not to be reused again during the operation.

The above description of the organ extraction process is highly detailed. The description can be misleading by making the process, seem much longer, and more complex than it actually is. The entire process is very simple and quick, as summarised by the following steps:

1. Open the endoTES sterile package.
2. INSERT the insertion handle down an established surgical port and inject the encapsulation bag into the patient.
3. ENCAPSULATE the specimen for extraction, and exteriorise the neck of the bag. Attach the morcellation handles to the cutting wires.
4. MORCELLATE the encapsulated specimen.
5. EXTRACT the tissue fragments using forceps, and remove the empty bag from the patient.
6. Dispose of the instrument.

On the basis of the steps described above, endoTES promises to be simple to use. The functional mechanics of the design are simple and easily understood. The human powered mechanics of endoTES ensure the surgeon is always totally in control. All of the required actions are deliberate, step by step manoeuvres, encouraging the user to become comfortable and confident with the device. The 'hands on' nature of the device makes endoTES more of a surgical hand tool than a complex automated system.

As the design is such a simple product, new users can be trained to use the device within the operative environment quickly and at minimal expense. The most skilful step required to be performed by the surgeon is encapsulation of the organ. Achieving this has been significantly improved with the reinforced bag mouth, visual highlighting of the bags mouth, and visual differentiation between the inner and outer surface of the bag.

6.3 Specification

There are four main components to endoTES:

- Insertion Handle
- Encapsulation Bag
- Morcellation Handles (2x)
- Packaging.

Each of these components is constructed of several smaller parts. The following sections describe the dimensions, surface finishes, materials, and production techniques of each of the parts.

The final specification of any product for production is influenced by the specific requirements of the selected tool makers and manufacturers. The following specification outlines the initially intended manufacturing processes. Prior to the design being produced, the commissioned toolmaker's and manufactures would be consulted to assess what modifications and design variations could be made to improve the manufacturing efficiency of the product.

6.3.1 The Insertion Handle

The Insertion Handle is comprised of seven parts. Each of these parts are listed and illustrated Figure 116. The material selected for each part would be decided in conjunction with the final selected resin supplier, however there are key qualities that any specified material must comply with:

- Suitable for gamma sterilisation.
- Non-toxic and suitable for use internally on a patient.
- Stable and reliable in transit.
- In failure the materials must bend and permanently deform rather than shattering into small fragments.
- Provide the desired product finish at an acceptable cost.
- Non-toxin producing during disposal incineration.

This list of material qualities is relevant for each part of the endoTES system (including the internal packaging).

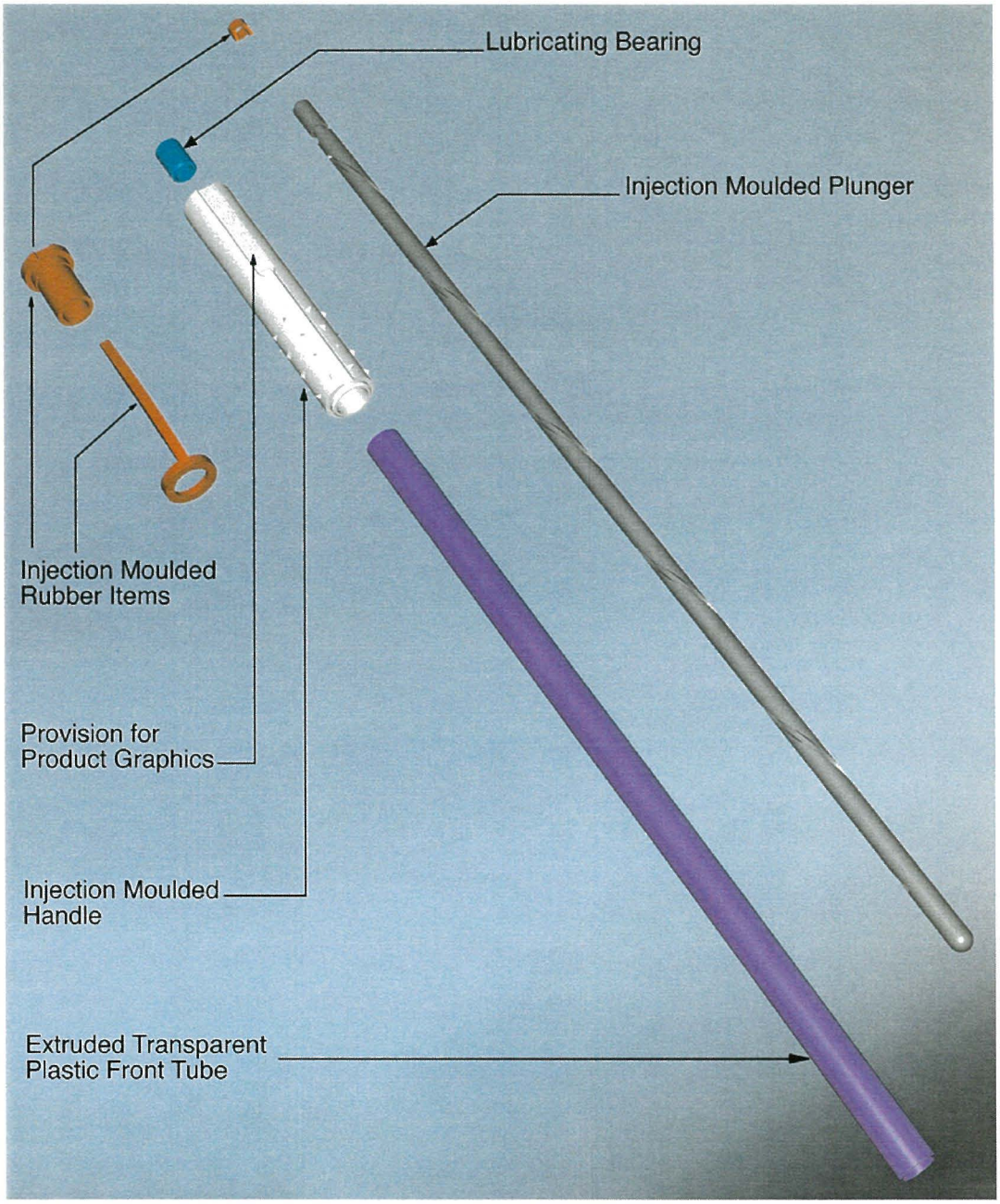


Figure 116 Exploded View of the Insertion Handle.

To prevent glare from the instrument during the operation, the surface finish on the front transparent tube of the insertion handle is matt. The handle shape allows the surgeon to grip the device between their thumb and fingers as observed in Section 5.4.2 (Video Analysis of a Surgeon Operating, p182). The cylindrical shape of the insertion handle allows the handle to be rotated through 360º without detrimentally affecting handle ergonomics.

Provision is made on the insertion handle for corporate identity logo's and text. The visual details existent on both the morcellation handle, and the insertion handle, help establish a product identity, and link each individual element as part of recognisable product group (Figure 107, p207).

To aid recognition of endoTES as an endoscopic implement, the visual appearance of the device, is not dissimilar from other disposable endoscopic instruments. The high quality product finish, and detailed aesthetic resolve, are tools utilised deliberately, to reinforce a perceived quality, to be associated with endoTES. To achieve this, an aesthetic treatment of smooth curves, contrasting with dynamic sharp lines has been applied. This is particularly evident on the morcellation handles, where the smooth, curved grip surface meets the crisp edge boundary of the top and side surfaces (Figure 118, p226).

6.3.2 The Encapsulation Bag

The Encapsulation Bag is a multi layer plastic bag. The multiple layers enable the cutting wires to be easily incorporated into the side walls of the bag during the production process. The bag layers are manufactured as per the four steps shown in Figure 117.

The bag is constructed of a high strength woven nylon, with a polyethylene coating (Figure 117). The fabric is highly resistant to puncturing or inadvertent abrasion. These qualities prevent diseased cells from contaminating the incision site or the operative cavity.

To prevent obscuring of intra-operational angiograms or X-rays, all materials are semi radio translucent. With extensive international sourcing, a suitable cutting filaments of semi radio translucent material may be found.

The design of the encapsulation bag is adaptable, allowing the removal of a wide range of different sized tissue specimens. A small encapsulation bag would be used for the smaller tissue specimens (e.g. inflamed appendix), while a large bag would be used for sizeable specimens (e.g. large spleen).

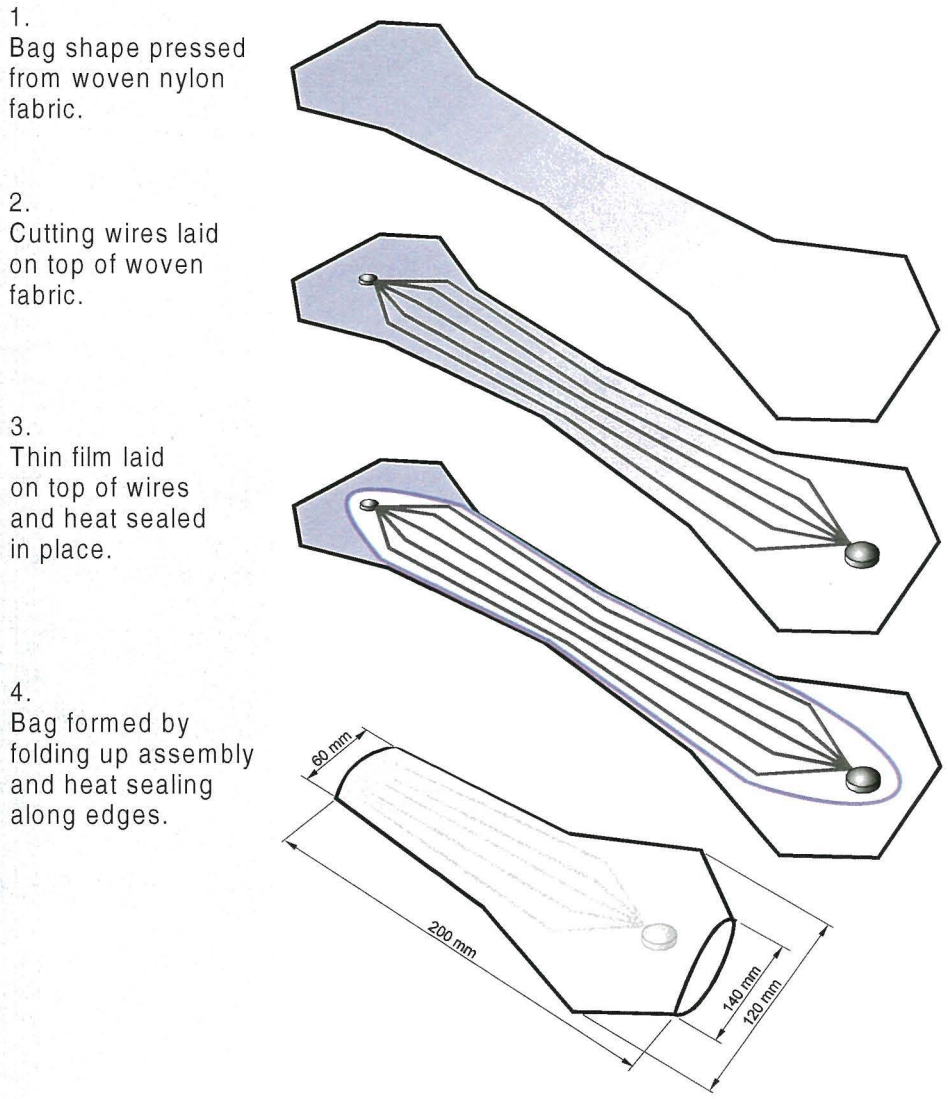


Figure 117 Manufacturing the Encapsulation Bag.

Unlike many of the devices analysed in Chapter 3, endoTES does not compromise the safety of the patient, the surgeon, or supporting medical staff. The cutting wires are 'blunt' and therefore there are no sharp blades or edges to inadvertently damage healthy structures, or break the sterile barrier of the surgeons gloves.

Should an instrument fail during insertion (e.g.: jamming in the cannula), then the device is removed from the patient and a new endoTES is utilised. Should the device fail before morcellation is complete (e.g.: wires become dislodged from end crimp) then the organ is removed out an enlarged incision as per the current technique.

As a disposable device endoTES must not be re-sterilised and reused. The following described design features supports this. The insertion handle, encapsulation bag, and cutting wires are all integral at manufacture, however during the morcellation process the cutting wires detach from the encapsulation bag, thereby making it physically impossible to reuse the device. The only items which could be reused after the operation are the morcellation handles. EndoTES comes packaged in a disposable kit form containing new: insertion handle, bag, and morcellation handles, and thus there is no motivation or cost benefit to reuse the morcellation handles.

6.3.3 The Morcellation Handles

The morcellation handles are made from two components. The two components can be either adhered, clipped, or moulded together during the production process (Figure 118).

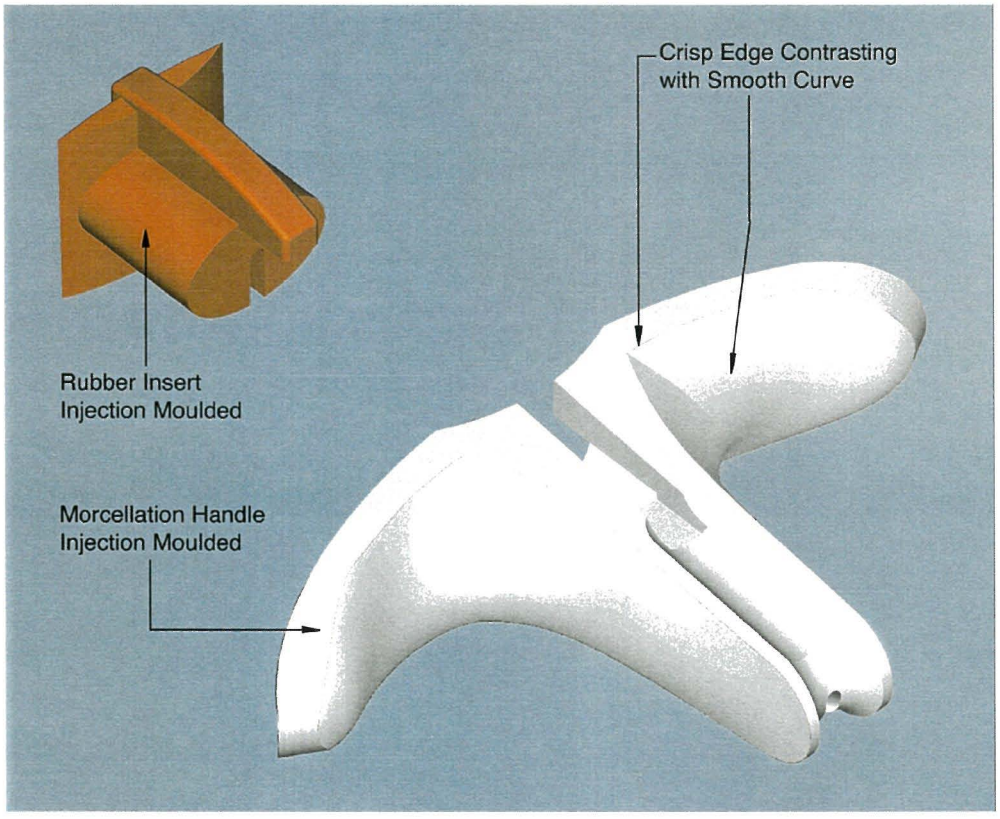


Figure 118 Exploded View of the Morcellation Handles.

Many of the components which make up the insertion handle and the morcellation handle would be manufactured from family dies (e.g. all rubber components), thus keeping tooling costs down. To aid with production assembly, each component is physically different, with distinctive and correct

orientations, specifically it is impossible to attach any part in the wrong location, because they simply will not fit.

A final sale cost, less than a disposable trocar is easily achievable due to the simple design and low number of parts. The design will be seen as an implement which saves money by reducing the cost incurred through longer hospital stays and recovery periods. The low number and small size of the components, makes the product acceptable for single use.

The physical nature of endoTES allows for the design to reach the widest possible market. As a single product, endoTES has the ability to service laparoscopic, thoracoscopic, and similar paediatric procedures. As a single product, endoTES is not designed for one specific operative situation, rather it is a flexible surgical tool for the removal of large tissue specimens. The simplicity of the design provides very low tooling costs, thus allowing the design to be adapted for veterinarian applications.

6.3.4 The Packaging

The packaging consists of three layers (Figure 119). There is an outer cardboard box (layer 1), which contains multiple white cardboard endoTES packages. This white cardboard box (layer 2) is described as the External Packaging. Contained within the external packaging is a plastic tray with a sterile seal, described as the internal packaging (layer 3). Contained within the internal packaging is an inner secondary sterile plastic tray that actual endoTES product is attached to. The inner secondary sterile tray is designed to be placed onto the sterile instrument trays of the operating theatre. There is also a set of instructions for endoTES contained within the packaging.

The three layered package is designed to protect the package during transit, and in storage. The package is a rectangular shape which stacks simply on a shelf or floor, and tessellates within a box. The external packaging provides a barrier from excessive dust, moisture and is durable against rough handling, vibration, and shock.

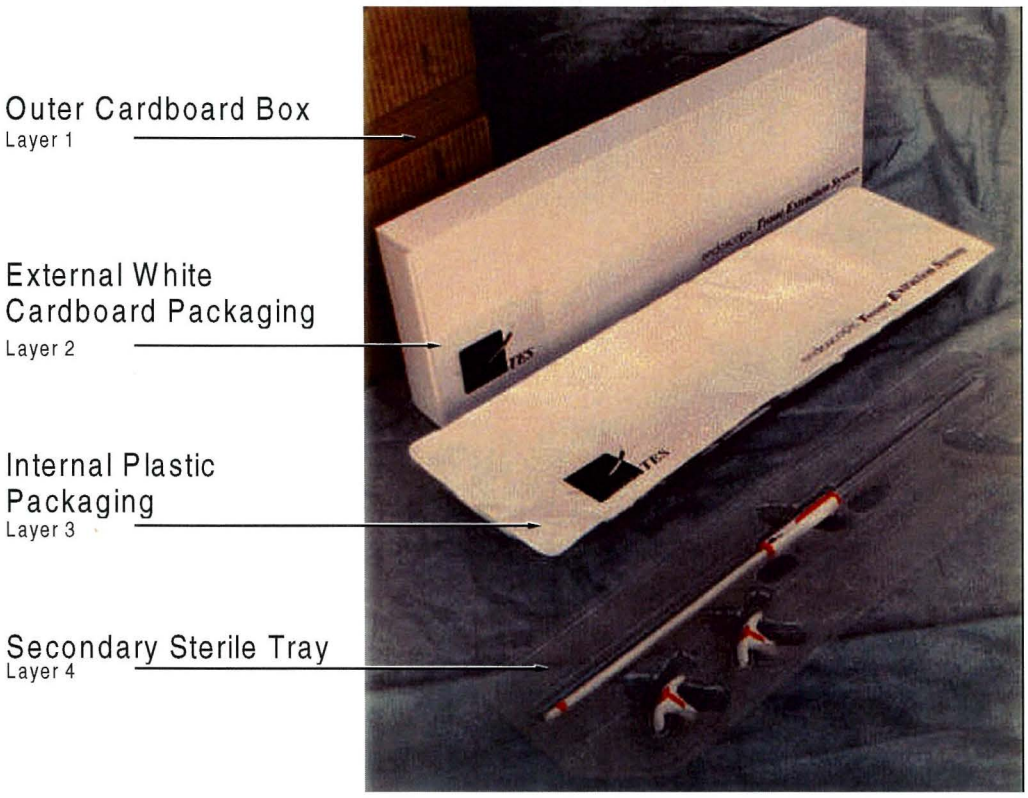


Figure 119 Exploded View of the Packaging.

Important design features of the package include:

- The design is acceptable for high volume, automated production.
- The selected materials are compatible with gamma sterilisation.
- The product components can only be placed in the package in one orientation - the correct one.
- There are no sharp corners or abrasive finishes on the package which might puncture an assembly workers glove.
- The product is constructed of a combination of recycled and virgin materials to reduce cost and improve the environmental aspects of the design.

As previously stated, a detailed packaging design is outside the scope of this thesis, however it is important to note that the final package design would include a complete description of the package contents. Included in this description would be the size of the contained encapsulation bag i.e. : small, medium, large, (or similar).

6.4 Summary

Using the research and knowledge established in Chapters 2 and 3, a design criteria checklist for the development of an endoscopic tissue extraction device was compiled in Chapter 4. A four stage research and design process (Chapter 5) was employed to develop an instrument suitable for the extraction of large tissue specimens and organs at endoscopy. The final proposed design was presented in Chapter 6.

The design proposed in Chapter 6 was presented, specified, and justified. The justification was based upon the design criteria checklist established in Chapter 4, and the results of the trials documented in Chapter 5.

CHAPTER 7

Conclusion

"Not every end is the goal. The end of a melody is not the goal, and yet if a melody has not reached its end, it has not reached its goal." (Nietzsche 1844 - 1900).

Research into the field of endoscopic surgery has been conducted, resulting in the identification of the problem of removing large tissue specimens, and organs at endoscopy (Chapter 1 and 2). Existing solution to this problem were investigated, and found to be unsatisfactory in terms of compromising patient quality of life, and / or patient safety (Chapter 3). A checklist of design criteria was established, documenting all of the constraints which a endoscopic tissue and organ extraction device must adhere to (Chapter 4). A four stage research and design process was employed to develop a new product for the extraction of large tissue specimens and organs at endoscopy. The design process incorporated trials to test suggested designs (Chapter 5). The final design was proposed, specified and justified based upon the results / observations / and conclusions of the trials (Chapter 6).

The subsequent chapter outlines the overall conclusions, contributions and recommendations resulting from the entire project: The chapter is divided into the following sections:

- Fulfilment of Aims and Objectives
- Conclusions about Endoscopic Surgery
- Conclusions about the Current Status of Tissue Extraction in Endoscopy
- Conclusions about the Design Methodology
- Conclusions about endoTES
- Recommendations for Industry
- Further Research

7.1 Fulfilment of Aim and Objectives

Based upon the design presented in Section 6.1 - 6.3, It is stated that the Thesis Aims and Objectives listed in Section 1.2, p19 have been fulfilled. Additionally the Thesis Specific Criteria listed in Section 4.8, p139, have been met. The following section substantiates these claims.

7.1.1 Fulfilment of Thesis Aim

Research into the field of endoscopic surgery has been conducted. (Chapters 1 and 2). The problem of removing large tissue specimens, and organs at endoscopy was identified (Section 1.3, p21). Existing solutions to this problem were found to compromise the quality of life, and / or the safety of patients (Sections 3.1 and 3.2, pp 85, 96).

The device designed (EndoTes) represents an internationally marketable device for the removal of large tissue specimens and organs in endoscopic surgery. EndoTES is suitable for use in thoracoscopic, laparoscopic, or paediatric surgery (Section 6.2.2, p211).

7.1.2 Fulfilment of Thesis Objectives

A new product for the extraction of large tissue specimens and organs in endoscopic surgery was conceived. As justified in Chapter 6, the proposed design addresses all of the necessary functional, ergonomic, user, marketing, production, and safety requirements, outlined in Chapter 4, without compromising the patients quality of life. EndoTES therefore presents a means for surgeons to provide better care for their patients.

A contribution to the body of knowledge for developing a medical instrument is presented throughout the entire thesis. An introduction to endoscopic surgery and the operative environment is given (Chapters 1 and 2). The design criteria checklist (Chapter 4) contains substantial information applicable to the development of any medical instrument. The documented design methodology (Chapter 5) and associated user studies, provide a case study of the process involved with design of a medical instrument.

Contributions to design theory and recommendations for further work are given (Chapter 7).

Multiple working prototypes of the design were constructed (Chapter 5). The design solution is therefore more than theoretical, it has been physically proven to perform the intended task (First achieved with Trial 18, Section 5.3.1, p169).

7.1.3 Fulfilment of Thesis Specific Criteria

The project has been completed within an acceptable time frame. All of the tasks required to be performed to complete the thesis have been conducted.

The project has remained on budget. Almost all of the required resources were available locally. The only significant difficulty was the inability to find a more efficient cutting wire to use in a final prototype.

The design has achieved the wider objectives of: adding to the body of knowledge available on the design of medical and endoscopic surgical instruments, being simple enough to enabled a working prototype to be constructed and trialed within a mock up surgical environment, and arriving at a marketable solution for which a provisional patent application was taken out by QUT in September 1995 (Provisional Patent Application Number: PN5415). Twelve months later a full international patent application was lodged (International Patent Application Number: PCT / AU96 / 00574).

In September 1996 the intellectual property associated with the project was successfully sold to a local consortium of medical device developers. The company Cut Safe Pty Ltd. (ACN 075 532 115) has been established with the intention of clinically trialing endoTES, leading to manufacturing or on-selling of the design.

7.2 Conclusions about Endoscopic Surgery

The benefits of endoscopic surgery (reduced trauma from: anaesthesia, blood loss, the therapeutic process, and surgical access, reduced hospital stay, reduced cosmetic damage, faster return to normal lifestyle,) over traditional open surgery, represents a significant improvement in the quality of life for patients undergoing treatment.

Endoscopic surgery will continue to be adopted in replacement of open procedures.

With the introduction of 3D viewing systems and improved instrument control, endoscopy will be applied to even the most complex operations (Cavaye, et.al., 1993). Organisations and medical groups are already discussing and developing thoracoscopic heart bypass procedures.

Comparisons of the cost of open versus closed procedures, have not been able to effectively consider all of the variables which make up the 'cost' of a procedure. After reading many studies it is the authors opinion that although endoscopic procedures may incur a slightly higher expense at the time of treatment (seldom over 15% higher), the cost savings from reducing a patients stay in hospital, and the reduced cost to the wider community from a shorter time of sick leave, result in a reduced overall cost to both the community and the patient (Silbertrust, 1993).

High use of disposable instruments will continue to raise questions about the cost of endoscopic procedures. Those involved in the development of endoscopic instruments must aim to contain equipment costs.

7.3 Conclusions about the Current Status of Tissue Extraction In Endoscopy

The existing process of removing tissue out an enlarged trocar incision is a compromise of the entire endoscopic approach to surgery. The technique is crude, rough, and causes considerable additional physical trauma to the patient. Using an oversized trocar is only a slight improvement on this process, and additionally, severely limits the size of the organs which can be extracted (Section 3.1.2, p86).

As demonstrated by the analysis conducted in Chapter 3 (Figure 42, p111), none of the available morcellation devices satisfy all of the essential product criteria. They all have insufficiencies in one or more of the following areas: compromise safety of patient or physician, inability to produce a specimen suitable for pathological examination, compromise of the benefits of the endoscopic approach, inability to remove a variety of tissue types, incomplete containment of diseased tissue, and non-transferable between laparoscopic, thoracoscopic and paediatric procedures.

The endoscopic organ and tissue extraction procedures described in Chapter 2 (Section 2.6 and 2.7, pp 62, 72) are being performed using the instruments analysed in Chapter 3 (Section 3.2, pp 96). With all of the shortcomings of these instruments demonstrated, it is justified that a market niche exists for an effective endoscopic tissue and organ extraction device.

7.4 Conclusions about the Design Methodology

The application of design methods to the problem of organ extraction in endoscopic surgery has produced a solution which satisfies, functional, user, marketing, production, and packaging requirements.

The time taken to complete the project could have been reduced with improved project documentation. Through use of a wider variety of recording mediums (video, sound, photographic), the entire design process could be enhanced and hastened (Sections 5.2.5, p165, 5.3.3, p172, and 5.4.9, p203).

The concept development book / diary kept a record of important project decisions and influences. To complement the concept development book, a written log containing literature review information pertinent to the design process needs to be continually maintained. The aim of the log book being to provide an ever changing discussion document incorporating the results of both the literature review and the design process.

Conscious control of the design and development process improved as the project progressed. Many of the early experiments were too crude and aimed to test too many variables simultaneously (Section 5.2.5, p165). The results of these early experiments were not adequately interpreted, and thus many tests had unnecessarily overlapping objectives. The improved planning of the later experiments, enabled well controlled experiments producing defined results e.g. Trials 35-36, p180.

Although this project has finished with a very promising solution, advice and caution are offered to future designers undertaking projects with equally tight constraints. When working to develop mechanisms and / or achieve a difficult functional objective, there is a real danger that a viable solution will not be found in the available time, or worse a solution will not be found at all. It is recommended that all designers beginning such projects be prepared for the possibility of such an outcome, by way of being able to adapt the project so that the research remains useful, enjoyable, and beneficial to the client / sponsoring organisation.

7.5 Conclusions about endoTES

On the basis of final design and justification presented in Chapter 6, it is stated that endoTES fulfils all of the necessary design criteria outlined in Chapter 4. Specifically and most importantly endoTES achieves theses key criteria:

- No additional incisions are required, neither is there any need to enlarge an existing incisions, thus none of the benefits of endoscopy (Section 1.1, p16) are forfeited.
- Removal of desired tissue without the risk of spreading diseased cells.
- A high quality extracted specimen is presented for pathological examination.
- Pneumoperitoneum is always maintained, thus the surgeon always maintains visualisation of the operation.
- Patient and physician safety is never compromised.
- The design is easy to use, and cost effective to manufacture.

On this basis, and in conjunction with the Trial results of Chapter 5, and the analysis of existing tissue extraction instruments conducted in Chapter 3, it can be stated that: EndoTES offers a significant improvement over the current methods of endoscopic organ extraction in terms of patient quality of life, and recovery time. Currently patients quality of life is being compromised, as there is no product available which adequately addresses the problem of removing large tissue specimens or organs through established surgical ports (Section 3.1 - 3.2, pp 85-112).

EndoTES represents a preliminary solution. The design remains to be tested on animals or on humans in a clinical medical environment under controlled supervision. Following such testing, it is expected that minor adjustments would be made to the product specification. An example of such an adjustment has been presented during follow-up testing (conducted in the final stages while actually writing this thesis) on human fibroids, which have indicated that a more aggressive cutting wire will be required to cope with the extremely tough tissues.

It is conceivable that endoTES will be used when appropriate in all of the following operations:

- cholecystectomy (gall bladder)
- hysterectomy (female reproductive organs)
- nephrectomy (kidneys)
- splenectomy (spleens)
- appendectomy (when the appendix is extremely inflamed)
- resection of mediastinal masses (thoracic masses and tumours)
- and any other operations which involve the removal of a large tissue specimen from within the patient.

Based on the fact that:

- endoTES may be applicable in many of these procedures.
- That over 500 000 people had their gall bladder removed in 1993 (Section 1.3 p22),

it can be envisaged that potential market for the device appears diverse and substantial.

7.6 Recommendations for Industry

The process of developing endoTES, has contributed to the body of knowledge, applicable to the medical instrument design and development industry. The following recommendations based on research and observations made over the entirety of the thesis:

The design criteria listed in Chapter 4 presents an extensive summary of constraints and criteria which must be taken into account when designing an endoscopic tissue extraction system. Many of the items noted in Chapter 4 can be used when designing any sterile surgical device. This list will provide an useful starting point for anyone designing a surgical product.

When designing an endoscopic instrument, the implement should fit down a 10mm or smaller surgical port, thus making the instrument useful for both thoracoscopic and paediatric applications, and substantially increasing market size.

Surgeons rotate endoscopic instruments through 360° about their longitudinal axis in total disregard of the intended handle grip features such as finger holes (Figure 87, p183). Handles must be designed to facilitate comfortable and controlled handling when being used at any rotational angle.

There must be a tactile mark on the handle of endoscopic instruments to correspond directly with the movements of the tip of the implement.

The latex gloves worn by surgeons and nurses can pinch very easily (Figure 91, p189). If two surfaces slide past each other then there must be a recess between the surfaces to prevent the gloves being pinched (Figure 111b, p213, Figure 120).

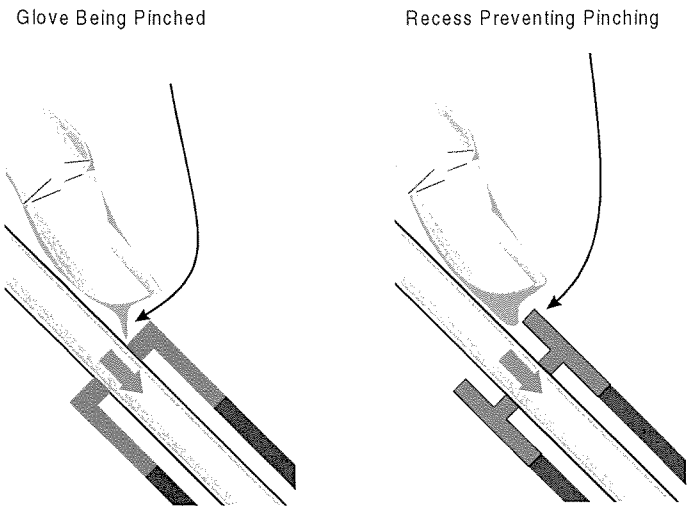


Figure 120 Avoiding Pinching Surgical Gloves.

Disposable instruments are being cleaned and re sterilised for reused by some hospitals in an attempt to reduce costs. Such actions are extremely dangerous to the patients health, and also present legal issues to: the physician, the health care provider, and the instrument manufacturer. Designers can help stop this disconcerting practise two ways:

- Provide design solutions which are economically and environmentally justifiable, thereby removing the motivation to reuse a disposable product.

- Ensure that all designs intended as disposable products, have in-built self destruction / safety features so that it is physically impossible to reuse the instrument.

7.7 Further Research

A study is required by a qualified individual into the effects of morcellating a tissue specimen prior to post-operative pathological examination. It is predicted that such a study will quash any concerns regarding specimen quality, currently being raised by a small number of individuals within the medical industry.

The safety of medical products is regulated by two means: International Standards, and Regulation Authorities such as the Federal Drug Authority in the United States (Estrin, 1990). New Standards are not usually written until a new product is developed and released, (e.g. automobile safety standards did not exist until automobiles became common and widely used). Endoscopic tissue and extraction devices are very new (none found prior to 1992), and at present (1996) no international standard on the design requirements of an such an implement exists. There is scope for instrument manufacturers and health providers, to establish international standards regarding endoscopic instruments, and more specifically, instruments for the extraction of large tissue specimens at endoscopy.

All of the possible applications of endoTES need to be investigated and confirmed by a group of physicians, including possible applications which may become available in the next five years. Following this an accurate marketing study into the expected annual sale units per year over the next five-ten years needs to be conducted.

The quantities of material consumed by the health industry are enormous. The use of more environmental friendly materials and practises within the surgical / medical industry requires investigation.

There is a market niche for the development of a software model capable of conducting a quantitative comparative cost analysis between different surgical instruments. The ability to evaluate the cost (of both the direct cost to the patient, and the wider indirect cost to the community) would enable anyone involved in medical research and development to more effectively evaluate their designs for appropriateness and efficiency.

EndoTES requires extensive clinical testing, and further development. The necessary processes need to be instigated to commercialise the project and pursue its adoption into medical practise. With continued development and clinical trialing, endoTES may represent a way to significantly improve patients quality of life.

Glossary

Bullae:	A bubble like structure. Often pertaining to the lungs.
Cholecystectomy:	Surgical incision into the gall bladder.
Coagulation:	Clotting, the conversion of a fluid into a jelly like substance.
Contextual Environment:	The environment in which a product is used.
Cystoscopy:	Visual examination of the interior of the urinary bladder by means of a cystoscope.
Design Freeze:	The point in time at which design development process is stopped.
Dissection:	To cut apart.
Electrocautery:	An instrument for cauterising tissue in which a metal wire is heated by a current of electricity.
Electrocoagulation:	The hardening of tissues induced by high frequency currents.
Endoscopy:	Inspection of the interior of a hollow organ or cavity by means of an endoscope.
Insufflation:	The filling of a cavity with a gaseous substance.
Intercostal Space:	The space located between successive ribs.
Intra-aluminal:	Within the lumen of a tubular structure
Laparonomy:	Surgical incision through any part of the abdominal wall.
Laparoscopy:	Visualisation of the contents of the abdominal cavity by means of an endoscope.
Lavage:	The washing out of a cavity or hollow organ.
Ligation:	The tying of a blood vessel.

Lumen:	The interior space of a tubular structure.
Mobilisation:	Making a part movable.
Morbidity:	The condition of being diseased.
Morcellation:	The act of reducing a large object into smaller fragments.
Multiparous:	Having born two or more offspring in separate pregnancies.
Outpatient:	A patient treated in a hospital or medical centre without being admitted.
PaCO2:	A relative measure of the amount of carbon dioxide in the blood stream.
Paediatrics:	The branch of medicine concerned with the care and development of children and the treatment their diseases.
Parential Pleura:	The layer of membrane lining the walls of the chest cavity.
Pelvic Inflammatory Disease:	Inflammation in the pelvic cavity - especially of the female reproductive organs.
Peritoneal Cavity:	The cavity encompassing the abdominal and pelvic cavities and the associated viscera.
Pleurectomy:	Incision into the pleural space.
Pleural Space:	The cavity containing the lungs.
Pneumoperitoneum:	The presence of air or gas in the peritoneal cavity.
Pneumothorax:	The presence of air of gas in the pleural cavity.
Reanastomosis:	A connection between two tubular structures. e.g. veins or intestines.

Recurrent Spontaneous Pneumothorax:	The recurrent presence of air or gas in the pleural cavity typically caused by a perforation of the lungs.
Retroperitoneal:	Located behind the Peritoneum.
Suturing:	To stitch and unite two surfaces.
Sympathectomy:	Surgical removal of a portion of a sympathetic nerve.
Systemic Disease:	Relating to or affecting the entire body.
Thoracoscopy:	Visual examination of the pleural cavity by means of an endoscope.
Trendelenberg Position:	Position in which the patient lies on their back on an operating table, inclined at an angle, with their head lower than the rest of their body.
Vagotomy:	Interruption of the operation of the function of the vagus nerve.
Visceral:	Pertaining to the internal organs.

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Appendices

Appendix 1 List of Endoscopic Procedures

(Hirsch 1992)

Laparoscopic Procedures

Female Reproductive Organs:

- Tubal Sterilisation
- Adhesolysis
- Treatment of Endometriosis
- Myomectomy
- Ovarian Cystectomy
- Salpingectomy
- Salpingostomy and other fertility promoting procedures
- Oophorectomy
- Management of ectopic pregnancy
- Biopsy
- Adexectomy

Appendix

- Appendectomy

Gall Bladder

- Cholecystectomy
- Choledochotomy

Urinary System

- Nephrectomy
- Unroofing and marsupialisation of cysts
- Nephroureterectomy
- Bladder Repair
- Vesical diverticulectomy
- Adrenalectomy

Intestines

- Vagotomy
- Jejunostomy
- Resection of colon
- Resection of rectum
- Colostomy

Stomach
- Repair of perforated ulcers
- Vagotomy

Abdominal Wall
- Repair of hernias

Pancreas
- Cholecystenterostomy
- Cholecystjejunostomy

Male Reproductive Organs
- Lymphadenectomy
- Varicocelectomy
- Prostatectomy
- Drainage of Lymphoceles

Liver
- Aspiration or excision of cysts

Esophagus
- Fundoplication
- Cardiomyotomy
- Laparoscopically assisted esophagectomy

Spleen
- Splenectomy

Thoracoscopic Procedures

Thoracic cavity
- Pleurectomy
- Lysis of adhesions
- Excision and ligation of pleural bullae
- Treatment of spontaneous pneumothorax
- Debridement of empyema

Lung

Cyst drainage
Biopsies
Lobectomy

Esophagus
Esophagotomy
Esophagael myotomy
Treatment of perforation

Nervous System
Cervical sympathectomy

Hysteroscopy

Female Reproductive Organs
Endometrial ablation and resection
Excision of endometrial polyps and submucous fibroids
Division of endometrial adhesions
Removal of IUD or foreign bodies
Sterilisation

Falloposcopy

Fallopian Tubes
Treatment of obstruction

Ureteroscopy

Urinary Tract
Treatment of bladder and ureteral stones

Colonoscopy

Lower Gastrointestinal Tract
Treatment of bleeding and obstruction
polypectomy
excision of tumours

Cystoscopy

Bladder

Excision of lesions and tumours

Endoscopy

Upper gastrointestinal tract

Treatment of esopheal bleeding and obstruction

Percutaneous gastrostomy

Tracheobronchial Tree

Removal of obstruction

Larynx

Removal of tumours and lesions

Partial aryteroidectomy

Face and Sinuses

Ethmoidectomy

Sphenoethmoidectomy

Removal of nasal polyps

Treatment of inflammation

Optic nerve and orbital decompression

Brain

Removal of tumours

Lachrymal Glands

Dacryocystorhinostomy

Conjunctivodacryostorhinostomy

Appendix 2 Ethicon Endosurgery Product Catalogue

johnson&johnson
MEDICAL PTY. LTD. A.C.N. 000 160 403

Mechanical Products

ETHICON ENDO-SURGERY

Johnson & Johnson MEDICAL PTY. LTD. A.C.N. 000 160 401

Item	Code	Description	Sales unit	Price for 1–2 sales units	Price for 3–5 sales units	Price for 6–11 sales units	Price for 12+ sales units

SKIN STAPLERS - DISPOSABLE

PROXIMATE* SKIN STAPLERS

83769	PTW35	Skin Stapler - 35 Staples	BX/6	127.00			
83766	PPW55	Skin Stapler - 55 Staples	BX/6	175.00			
83764	PRW35	Skin Stapler - Rotating Head 35 Staples	BX/6	289.00			

SKIN STAPLE EXTRACTOR

83765	PSX	Skin Staple Extractor	BX/12	99.00			

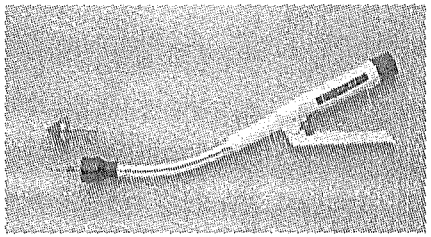
PURSE STRING DEVICES

75250	ESS-91G	Purse String Suture	BX/12	91.00			
83926	EH40	Purse String Clamp	EACH	1250.00			

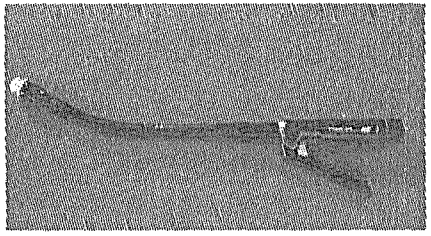
CIRCULAR STAPLERS - DISPOSABLE

PROXIMATE* ILS CURVED CIRCULAR STAPLERS

89603	CDH21	21 mm Curved Detachable Head	EACH	549.00	496.00	569.00	449.00
89602	CDH25	25 mm Curved Detachable Head	EACH	549.00	496.00	569.00	449.00
89601	CDH29	29 mm Curved Detachable Head	EACH	549.00	496.00	569.00	449.00
89600	CDH33	33 mm Curved Detachable Head	EACH	549.00	496.00	569.00	449.00
84077	ECS21	"Stealth" Endoscopic Stapler - 21 mm Cvd, Detach Head, Aqua	EACH	571.00	543.00	514.00	471.00
84078	ECS25	"Stealth" Endoscopic Stapler - 25 mm Cvd, Detach Head, White	EACH	571.00	543.00	514.00	471.00
84079	ECS29	"Stealth" Endoscopic Stapler - 29 mm Cvd, Detach Head, Blue	EACH	571.00	543.00	514.00	471.00
84002	ECS33	"Stealth" Endoscopic Stapler - 33 mm Cvd, Detach Head, Green	EACH	571.00	543.00	514.00	471.00



Curved Circular CDH33



"Stealth" Curved Circular ECS25

Price effective 11/12/95

*TRADEMARK

Item	Code	Description	Sales Unit				

PROXIMATE* ILS STRAIGHT CIRCULAR STAPLERS

89604	SDH21	21 mm Straight Detachable Head	EACH	476.00	428.00	404.00	399.00
89605	SDH25	25 mm Straight Detachable Head	EACH	476.00	428.00	404.00	399.00
89606	SDH29	29 mm Straight Detachable Head	EACH	476.00	428.00	404.00	399.00
89607	SDH33	33 mm Straight Detachable Head	EACH	476.00	428.00	404.00	399.00

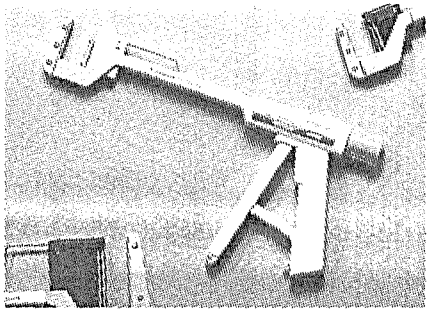
SIZERS

84028	EH91	Dilator/Sizer - 21 mm	EACH	375.00			
84027	EH92	Dilator/Sizer - 25 mm	EACH	375.00			
84030	EH93	Dilator/Sizer - 29 mm	EACH	375.00			
84029	EH94	Dilator/Sizer - 33 mm	EACH	375.00			

LINEAR STAPLERS - DISPOSABLE, RELOADABLE

PROXIMATE* LINEAR STAPLERS

83854	TL30	Linear - 30 mm Reloadable (white)	EACH	205.00	186.00	174.00	166.00
83839	TLH30	Linear - 30 mm Heavy Reloadable (yellow)	EACH	205.00	186.00	174.00	166.00
83866	TLV30	Linear - 30 mm Vascular Reloadable (red)	EACH	205.00	186.00	174.00	166.00
83858	TL60	Linear - 60 mm Reloadable (white)	EACH	218.00	196.00	186.00	176.00
89851	TLH60	Linear - 60 mm Heavy Reloadable (yellow)	EACH	218.00	196.00	186.00	176.00
83863	TL90	Linear - 90 mm Reloadable (white)	EACH	240.00	218.00	207.00	198.00
83846	TLH90	Linear - 90 mm Heavy Reloadable (yellow)	EACH	240.00	218.00	207.00	198.00

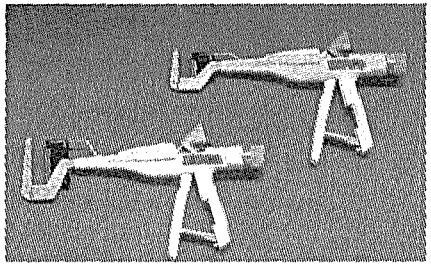


Linear Stapler TLV30

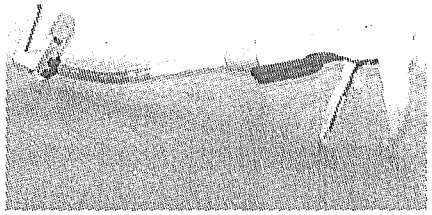
Price effective 11/12/95

*TRADEMARK

Johnson & Johnson MEDICAL PTY. LTD. A.C.N. 000 160 403



Linear Stapler TP60

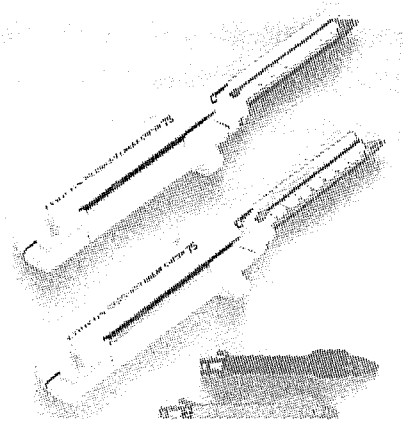


Articulating Linear Stapler AX556

Item	Code	Description	Sales unit	1–2 sales units	3–5 sales units	6–11 sales units	12+ sales units
PROXIMATE* PLUS LINEAR STAPLERS							
89958	TP30	Linear - 30 mm Plus Reloadable (white)	EACH	261.00	235.00	221.00	209.00
89955	TPH30	Linear - 30 mm Plus Heavy Reloadable (yellow)	EACH	261.00	235.00	221.00	209.00
89961	TPV30	Linear - 30 mm Plus Vascular Reloadable (red)	EACH	261.00	235.00	221.00	209.00
89959	TP60	Linear - 60 mm Plus Reloadable (white)	EACH	273.00	245.00	231.00	220.00
89956	TPH60	Linear - 60 mm Plus Heavy Reloadable (yellow)	EACH	273.00	245.00	231.00	220.00
89957	TPH90	Linear - 90 mm Plus Heavy Reloadable (yellow)	EACH	279.00	251.00	238.00	220.00
PROXIMATE* ACCESS 55 ARTICULATING LINEAR STAPLERS							
57110	AX55B	Articulating Linear 55 mm Stapler (not reloadable) - regular tissue	EACH	555.00	538.00	519.00	509.00
57111	AX55G	Articularing Linear 55 mm Stapler (not reloadable) - thick tissue	EACH	555.00	538.00	519.00	509.00
PROXIMATE* LINEAR STAPLER RELOAD CARTRIDGES							
08803	TR30	30 mm Cartridges (white)	EACH	148.00	131.00	123.00	116.00
08802	TRV30	30 mm Vascular Cartridges (red)	EACH	148.00	131.00	123.00	116.00
08791	TRH30	30 mm Heavy Cartridges (yellow)	EACH	148.00	131.00	123.00	116.00
08800	TR60	60 mm Cartridges (white)	EACH	148.00	131.00	123.00	116.00
08784	TRH60	60 mm Heavy Cartridges (yellow)	EACH	148.00	131.00	123.00	116.00
08801	TR90	90 mm Cartridges (white)	EACH	148.00	131.00	123.00	116.00
08785	TRH90	90 mm Heavy Cartridges (yellow)	EACH	148.00	131.00	123.00	116.00

Price effective 11/12/95

*TRADEMARK



Linear Cutter TLC75

Item	Code	Description	Sales unit	Units			

LINEAR CUTTERS - DISPOSABLE, RELOADABLE

PROXIMATE* LINEAR CUTTERS WITH SAFETY LOCKOUT

89009	TLC55	55 mm, Blue 1.5 mm Staple	EACH	215.00	194.00	184.00	173.00
89007	TCT55	55 mm, Green 2.0 mm Staple	EACH	215.00	194.00	184.00	173.00
21107	TVC55	55mm, White, Vascular, 1.0mm Staple	EACH	215.00	194.00	184.00	173.00
89006	TL455	55 mm, Four Row, No Knife, Blue 1.5 mm Staple	EACH	215.00	194.00	184.00	173.00
84088	T4T55	55 mm, Four Row, No Knife, Green 2.0 mm Staple	EACH	215.00	194.00	184.00	173.00
89882	TLC75	75 mm, Blue 1.5 mm Staple	EACH	293.00	263.00	250.00	234.00
89881	TCT75	75 mm, Green 2.0 mm Staple	EACH	293.00	263.00	250.00	234.00
89879	TL475	75 mm, Four Row, No Knife, Blue 1.5 mm Staple	EACH	293.00	263.00	250.00	234.00
84089	T4T75	75 mm, Four Row, No Knife, Green 2.0 mm Staple	EACH	293.00	263.00	250.00	234.00

PROXIMATE* LINEAR CUTTER RELOAD CARTRIDGES

08786	TCR55	55 mm, Blue 1.5 mm Staple	EACH	155.00	148.00	142.00	140.00
08787	TRT55	55 mm, Green 2.0 mm Staple	EACH	155.00	148.00	142.00	140.00
21106	TVR55	55mm, White, Vascular, 1.0mm Staple	EACH	155.00	148.00	142.00	140.00
08788	TCR75	75 mm, Blue 1.5 mm Staple	EACH	180.00	173.00	166.00	165.00
08789	TRT75	75 mm, Green 2.0 mm Staple	EACH	180.00	173.00	166.00	165.00

LIGATION

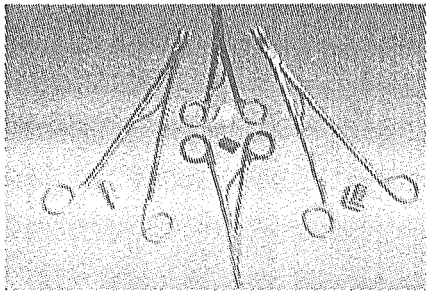
LIGACLIP* LIGATION CLIPS

83966	LT100	Clips - Titanium, 36 Cartridges, Small Blue 3 mm	BX/216	215.00			
83975	LT102	Clips - Titanium, 15 Cartridges, Small Blue 3 mm	BX/300	318.00			
83967	LT200	Clips - Titanium, 36 Cartridges, Medium White 5 mm	BX/216	251.00			
83968	LT300	Clips - Titanium, 18 Cartridges, Med-Large Green 9 mm	BX/108	182.00			
83969	LT400	Clips - Titanium, 18 Cartridges, Large Yellow 12 mm	BX/108	208.00			
17130	LT202	Clips - Titanium, 15 Cartridges, Medium White 5mm	BX/300	348.00			

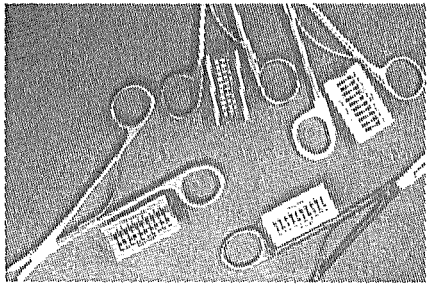
Price effective 11/12/95

*TRADEMARK

Johnson & Johnson MEDICAL PTY. LTD. A.C.N. 000 160 401



Ligaclip Applier LC207

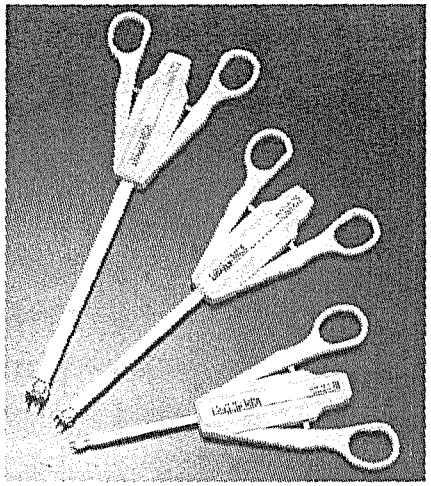


Absolok Applier AP310

Price effective 11/12/95

Item	Code	Description	Sales unit	1–2 sales units	3–5 sales units	6–11 sales units	12+ sales units
LIGACLIP* TITANIUM CLIP APPLIERS							
83900	LC105	Clip Applier - 146 mm (5"), Small	EACH	264.00			
83901	LC107	Clip Applier - 191 mm (7"), Small	EACH	264.00			
83902	LC205	Clip Applier - 146 mm (5"), Medium	EACH	264.00			
83903	LC207	Clip Applier - 191 mm (7"), Medium	EACH	264.00			
83904	LC210	Clip Applier - 267 mm (10"), Medium	EACH	264.00			
83917	LC307	Clip Applier - 191 mm (7"), Medium-Large	EACH	264.00			
83918	LC310	Clip Applier - 267 mm (10"), Medium-Large	EACH	264.00			
83907	LC407	Clip Applier - 191 mm (7"), Large	EACH	264.00			
83908	LC410	Clip Applier - 267 mm (10"), Large	EACH	264.00			
83897	LC800	Clip Base - All Sizes	EACH	264.00			
ABSOLOK* AND PDS LIGATION CLIPS							
83931	AP100	Clips - PDS - 6 Cartridges - Small Blue 3 mm	BX/60	307.00			
83934	AP200	Clips - PDS - 6 Cartridges - Medium White 5 mm	BX/60	307.00			
83936	AP300	Clips - PDS - 6 Cartridges - Medium-Large Green 7 mm	BX/60	307.00			
83940	AP400	Clips - PDS - 6 Cartridges - Large Yellow 11 mm	BX/60	307.00			
PDS CLIP APPLIERS							
83932	AP105	Clip Applier - 146 mm (5")- Small	EACH	264.00			
83933	AP107	Clip Applier - 191 mm (7")- Small	EACH	264.00			
83935	AP207	Clip Applier - 191 mm (7") - Medium	EACH	264.00			
83938	AP210	Clip Applier - 267 mm (10")- Medium	EACH	264.00			
83937	AP307	Clip Applier - 191 mm (7")- Medium-Large	EACH	264.00			
83939	AP310	Clip Applier - 267 mm (10")- Medium-Large	EACH	264.00			
83941	AP407	Clip Applier - 191 mm (7")- Large	EACH	264.00			
83942	AP410	Clip Applier - 267 mm (10") - Large	EACH	264.00			

*TRADEMARK



Multiclip Applier MCM30

Item	Code						

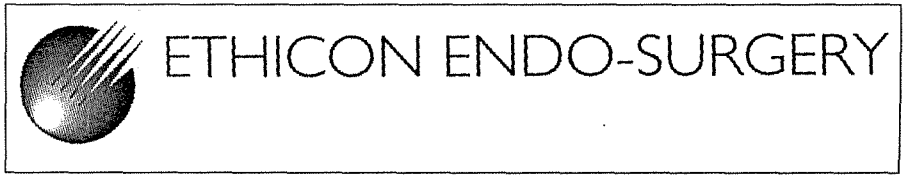
CLIP APPLIERS - DISPOSABLE

08799	TIM20	Multiclip - 20 x 6 mm Titanium Med Clips, Reloadable	EACH	137.00	132.00	120.00	105.00
08790	TIR20	Multiclip Open Cart - 20 Clip Cartridge 20 x 6 mm Clips	EACH	73.00	70.00	67.00	65.00
99200	MCS20	Multiclip 23 cm (9") - 20 x 3 mm Titanium Clips	EACH	158.00	141.00	136.00	134.00
99201	MSM20	Multiclip 23 cm (9") - 20 x 5 mm Titanium Clips	EACH	158.00	141.00	136.00	134.00
99202	MCM20	Multiclip 29 cm (11 1/2") - 20 x 5 mm Titanium Clips	EACH	158.00	141.00	136.00	134.00
99203	MCM30	Multiclip 29 cm (11 1/2") - 30 x 5 mm Titanium Clips	EACH	165.00	154.00	152.00	148.00
99204	MCL20	Multiclip 33 cm (13") - 20 x 12 mm Titanium Clips	EACH	165.00	154.00	152.00	148.00

Price effective 11/12/95

Johnson & Johnson
MEDICAL PTY. LTD. A.C.N. 000 160 403

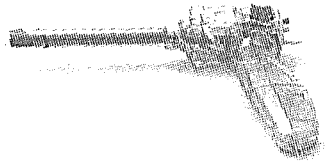
Endosurgical Products



Johnson & Johnson MEDICAL PTY. LTD. A.C.N. 000 160 403

Endo Linear Cutter EZ35

Endo Linear Cutter EZ45



Endo Cutter Reloads Z445

Price effective 1/12/95

Item	Code	Description	Sales unit	1–2 sales units	3–5 sales units	6–11 sales units	12+ sales units

ENDO LINEAR CUTTERS

ENDOPATH* 35 MM LINEAR CUTTER

84797	EZ35B	35 mm Cutter - Blue 1.5 mm Staple	EACH	426.00	422.00	406.00	404.00
84083	EZ35W	35 mm Cutter - White, Vascular, 1.0 mm Staple	EACH	426.00	422.00	406.00	404.00

ENDOPATH* 45 MM LINEAR CUTTER

57000	EZ45B	45mm Cutter -Blue 1.5mm Staple	EACH	518.00	508.00	497.00	487.00
57001	EZ45G	45mm Cutter -Green 2.0mm Staple	EACH	518.00	508.00	497.00	487.00

ENDOPATH* 60 MM LINEAR CUTTER

84048	ELC60	60 mm Cutter - Blue 1.5 mm Staple	EACH	520.00	492.00	465.00	438.00
84047	EL460	60 mm Four Row - Blue 1.5 mm Staple	EACH	520.00	492.00	465.00	438.00
84046	ETC60	60 mm Cutter - Green, 2 mm Staple, Thick Tissue	EACH	520.00	492.00	465.00	438.00
84045	ET460	60 mm Four Row - Green 2 mm Staple, Thick Tissue	EACH	520.00	492.00	465.00	438.00

ENDOPATH* 35 MM LINEAR CUTTER RELOAD CARTRIDGES

84094	ERU35	35 mm Cutter Cart - Blue 1.5 mm Staple	EACH	156.00	153.00	148.00	144.00
84093	EVU35	35 mm Vascular Cutter Cart - White 1.0 mm Staple	EACH	156.00	153.00	148.00	144.00

ENDOPATH* 45 MM LINEAR CUTTER RELOAD CARTRIDGES

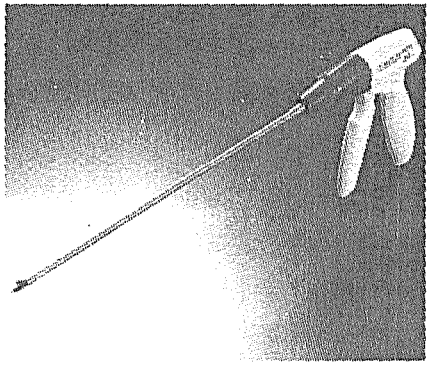
57010	ZR45B	45mm Cutter Cart - Blue 1.5mm Staple	EACH	179.00	175.00	167.00	163.00
57011	ZR45G	45mm Cutter Cart - Green 2.0mm Staple	EACH	179.00	175.00	167.00	163.00

ENDOPATH* 60 MM LINEAR CUTTER RELOAD CARTRIDGES

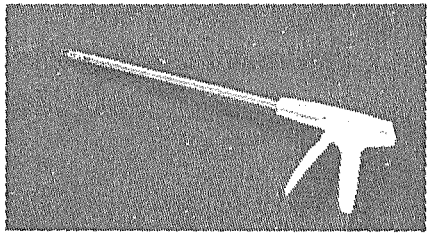
84044	ERU60	60 mm Cutter Cart - Blue 1.5 mm Staple	EACH	190.00	181.00	170.00	161.00
84043	ETU60	60 mm Cutter Cart - Green 2 mm Staple, Thick Tissue	EACH	190.00	181.00	170.00	161.00

*TRADEMARK

Stealth Curved Circular Stapler ECS29



Allport 5mm Clip Applier AL326



Multiclip Applier ER320

Item	Code	Description					

ENDOSCOPIC CIRCULAR STAPLERS - DISPOSABLE

84077	ECS21	"Stealth" Endoscopic Stapler - 21 mm Cvd, Detach Head, Aqua	EACH	570.00	543.00	514.00	471.00
84078	ECS25	"Stealth" Endoscopic Stapler - 25 mm Cvd, Detach Head, White	EACH	570.00	543.00	514.00	471.00
84079	ECS29	"Stealth" Endoscopic Stapler - 29 mm Cvd, Detach Head, Blue	EACH	570.00	543.00	514.00	471.00
84002	ECS33	"Stealth" Endoscopic Stapler - 33 mm Cvd, Detach Head, Green	EACH	570.00	543.00	514.00	471.00

ENDOSCOPIC MULTIPLE STAPLERS - DISPOSABLE

89503	EMS	Multistapler - 20 Staples, Rotating Head	EACH	369.00	331.00	314.00	306.00
84062	EAS	Articulating Multistapler - 25 Staples, Rotating Head	EACH	397.00	359.00	342.00	337.00
88502	ESX	Staple Extractor	EACH	4784.00			

ENDOSCOPIC CLIP APPLIERS

REUSABLE

83954	EL214	Clip Applier - 5 mm (14")- Medium Accepts Ligaclip Extra LT200 clips	EACH	1676.00			
83998	EL414	Clip Applier - 12 mm (14") - Large Accepts Ligaclip Extra LT400 clips	EACH	1676.00			
83952	AE314	Clip Applier - 7 mm (14") - Absolok* Med-Large Accepts Absolok PDS Absorbable Clips AP300	EACH	1817.00			

DISPOSABLE

84063	ER220	Multiclip - 20 Clips, Rotating Head - 6 mm Clips	EACH	315.00	284.00	267.00	256.00
89971	ER320	Multiclip - 20 Clips, Rotating Head - 9 mm Clips	EACH	315.00	284.00	267.00	256.00
84064	ER420	Multiclip - 20 Clips, Rotating Head - 12 mm Clips	EACH	320.00	293.00	275.00	264.00
17115	AL326	5mm Multiclip - 20 Clips Rotating Head - 10mm Clips	EACH	345.00	334.00	328.00	320.00
93960	LD320	Endo Ligate and Divide	EACH	346.00	313.00	293.00	283.00

Price effective 11/12/95

*TRADEMARK

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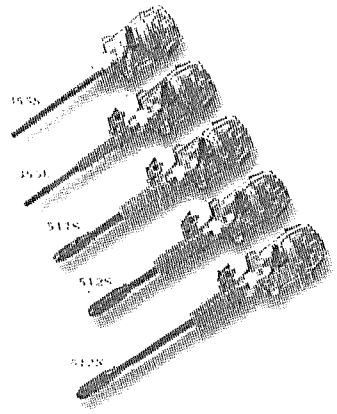
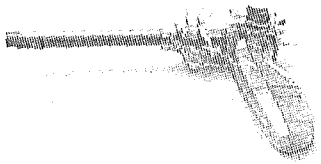
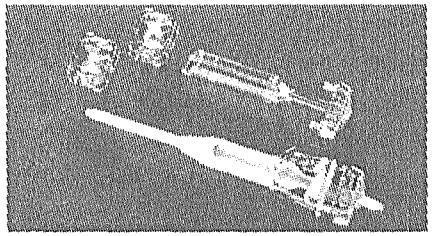


Tristar Trocars



Optiview Trocar 512H



Specimen Removal Trocar LTK33

Price effective 11/12/95

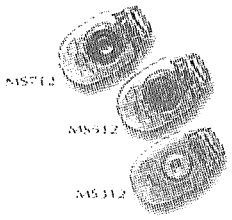
Item	Code	Description	Sales unit	Price for 1–2 sales units	Price for 3–5 sales units	Price for 6–11 sales units	Price for 12+ sales units

TROCARS - DISPOSABLE

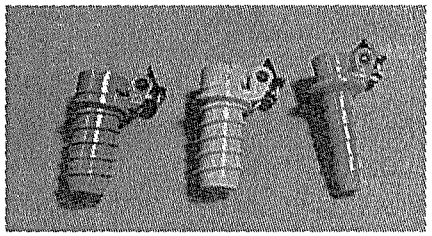
ENDOPATH* TROCARS

99881	355S	5 mm Trocar, 75 mm Long Cannula	BX/6	482.00			
99882	355L	5 mm Trocar, 100 mm Long Cannula	BX/6	482.00			
57017	355T	5mm Trocar, 75mm Long Cannula with Thread	BX/6	482.00			
99883	511S	10/11 mm Trocar, 100 mm Long Cannula	BX/6	582.00			
99884	512S	10/12 mm Trocar, 100 mm Long Cannula	BX/6	582.00			
99886	512X	10/12 mm Trocar, 150 mm Long Cannula	BX/6	582.00			
57016	512B	10/12mm Blunt Hasson Trocar	BX/6	706.00			
57018	512O	10/12mm OPTIVIEW* Trocar 100mm Long Cannula	BX/6	88.00			
57019	512H	10/12mm OPTIVIEW* Handled Trocar 100mm Cannula	BX/6	90.00			
83758	TT011	11 mm Thoracic Trocar	BX/6	245.00			
84073	TT012	12 mm Thoracic Trocar	BX/6	235.00			
55516	FP007	7 mm FLEXIPATH Trocar	BX/6	235.00			
55517	FP015	15 mm FLEXIPATH Trocar	BX/6	282.00			
55518	FP020	20 mm FLEXIPATH Trocar	BX/6	282.00			
55519	FPK01	15 mm FLEXIPATH Kit 1 x 15 mm FLEXIPATH obturator, 3 x 15 mm FLEXIPATH sleeves; 1 x TT012	EACH	115.00	111.00	107.00	101.00
55520	FPK02	15 mm FLEXIPATH Kit 1 x 15 mm FLEXIPATH obturator, 3 x 15 mm FLEXIPATH sleeves	EACH	115.00	111.00	107.00	101.00
55521	FPK03	20 mm FLEXIPATH Kit 1 x 20 mm FLEXIPATH obturator, 3 x 20 mm FLEXIPATH sleeves	EACH	115.00	111.00	107.00	101.00
84801	TEC18	18 mm Specimen Removal Trocar, No Stopcock	EACH	146.00	144.00	131.00	125.00
84067	LTK33	33 mm Specimen Removal Trocar	EACH	226.00	205.00	185.00	166.00

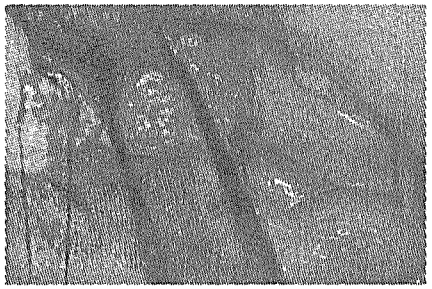
*TRADEMARK



Tristar II Fliptop Reducers



Stability Threads



Ultra Verres Needle UV120

Item	Code							

REDUCERS

17589	MS312	Flip Top Reducer - All size trocars reduced to 3.5 mm	BX/12	101.00			
16101	MS512	Flip Top Reducer - All size trocars reduced to 5.5 mm	BX/12	101.00			
17588	MS712	Flip Top Reducer - All size trocars reduced to 7.5 mm	BX/12	101.00			
84060	R1805	Reducer - 18 mm reduced to 5 mm	BX/6	67.00			
84061	R1810	Reducer - 18 mm reduced to 10 mm	BX/6	67.00			

STABILITY THREADS

17590	T355	Stability Thread for 5 mm trocar	BX/12	131.00			
17401	T511	Stability Thread for 10/11 mm trocar	BX/12	131.00			
17591	T512	Stability Thread for 10/12 mm trocar	BX/12	131.00			

INSUFFLATION NEEDLES - DISPOSABLE

12478	PN120	Pneumoneedle - 120 mm	BX/12	451.00			
17509	PN150	Pneumoneedle - 150 mm	BX/12	451.00			
83776	UV120	Ultra Verres Needle - 120 mm	BX/12	584.00			

CATHETERS

08792	EBC04	4.5 Cholang Balloon, 50 cm w/14 Gauge, 2 1/4 Catheter Introducer	EACH	118.00	113.00	103.00	87.00
08793	ECC05	4.5 Cholang, 50 cm 2 1/4 Catheter Introducer	EACH	106.00	102.00	96.00	93.00
84037	PCI	Catheter Introducer	EACH	120.00			

ENDO TRAINER

83983	ENDO1	Endo Trainer	EACH	1300.00			

Price effective 11/12/95

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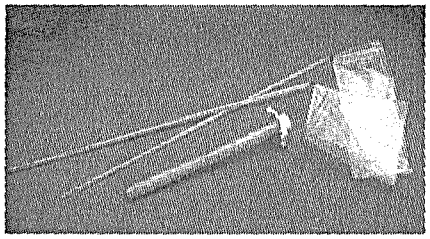
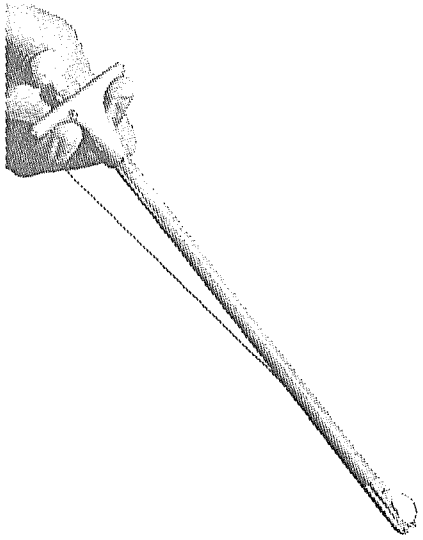
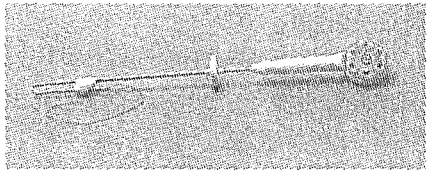


Endopouch EP44



Laurus Needle Driver ND260



ENDOJUDGE EJ010

Item	Code	Description	Sales unit	1–2 sales units	3–5 sales units	6–11 sales units	12+ sales units

ENDOPOUCH* SPECIMEN BAGS

17504	EP22	Specimen Retrieval Bag - Small, 5 x 5 cm (2" x 2")	BX/6	250.00	235.00		
17502	EP26	Specimen Retrieval Bag - Medium, 5 x 15 cm (2" x 6")	BX/6	250.00	235.00		
17506	EP44	Specimen Retrieval Bag - Large, 10 x 10 cm (4" x 4")	BX/6	250.00	235.00		
84927	ELI10	ENDOPOUCH* Introducer	BX/6	101.00			

ENDOJUDGE

57020	EJ010	ENDO-JUDGE 10mm Wound Closure Device	EACH	54.00	52.00	50.00	48.00
57021	EJ012	ENDO-JUDGE 12mm Wound Closure Device	EACH	54.00	52.00	50.00	48.00

LAURUS

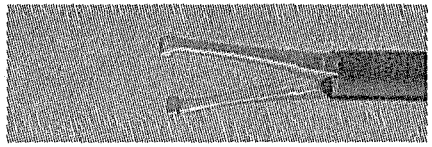
28545	ND260	LAURUS Needle Driver	EACH	95.00	89.00	84.00	77.00

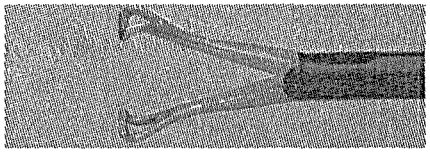
5 MM DISPOSABLE HANDHELD INSTRUMENTS

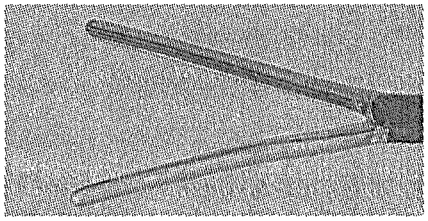
17587	BCD10	Cherry Dissector (3 per pkt, 12 pkts per box)	BX/36	398.00			
17507	BTD05	Blunt Dissector (3 per pkt; 12 pkts per box)	BX/36	398.00			
08684	DHS14	Scissors Hook With Cautery	EACH	167.00	159.00	145.00	125.00
08683	DMS15	Scissors Micro With Cautery	EACH	167.00	159.00	145.00	125.00
08783	DCS12	Metzenbaum Scissors Curved With Cautery	EACH	204.00	196.00	178.00	155.00
08688	DSG22	Small Grasper With Ratchet and Cautery	EACH	167.00	159.00	145.00	125.00
08718	DSG23	Large Grasper With Ratchet and Cautery	EACH	167.00	159.00	145.00	125.00
08687	DCD32	Curved Dissector With Cautery	EACH	167.00	159.00	145.00	125.00
08686	DSD33	Straight Dissector With Cautery	EACH	167.00	159.00	145.00	125.00
08685	DEX41	Claw Extractor With Ratchet	EACH	167.00	159.00	145.00	125.00
84031	ETM05	Endoscopic Tissue Manipulator	EACH	176.00	153.00	138.00	124.00
75796	SCD32	Short Curved Dissector	EACH	167.00	159.00	145.00	125.00
75799	SCS12	Short Curved Scissors	EACH	204.00	196.00	178.00	155.00
75797	SSD33	Short Straight Dissector	EACH	167.00	159.00	145.00	125.00
75800	SSG22	Short Straight Grasper	EACH	167.00	159.00	145.00	125.00

Price effective 11/12/95

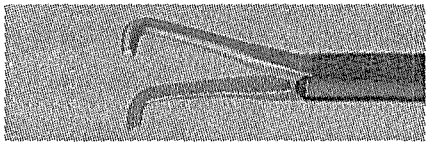
*TRADEMARK


Allis Clamp BA10


Babcock BB10


Bowel Clamp BC10


Metzenbaum Scissors BMS10


Right Angle BRK10

10 MM DISPOSABLE HANDHELD INSTRUMENTS

Item	Code	Description	Sales unit				
84091	AB10	Atraumatic Babcock	EACH	249.00	234.00	212.00	186.00
08798	BA10	Allis Clamp With Ratchet	EACH	233.00	224.00	203.00	176.00
08797	BB10	Babcock With Ratchet	EACH	233.00	224.00	203.00	176.00
08796	BC10	Bowel Clamp With Ratchet	EACH	233.00	224.00	203.00	176.00
84087	BMS10	Metzenbaum Scissors	EACH	255.00	244.00	224.00	216.00
08794	BRK10	Right Angle With Ratchet	EACH	233.00	224.00	203.00	176.00

Price effective 11/12/95

*TRADEMARK

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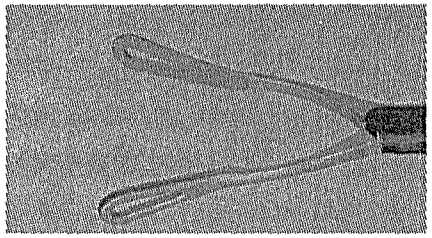
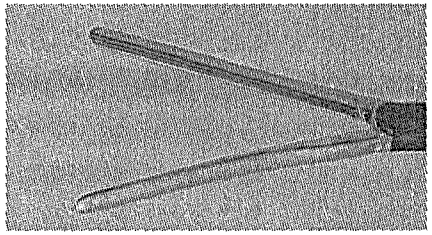
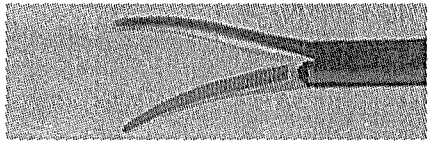


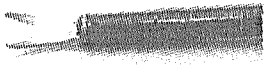
Lung Clamp ENDLC



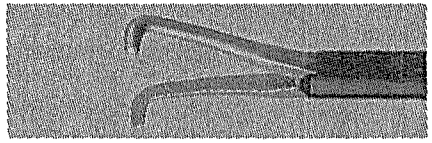
Glassman Clamp TGC10



Curved Kelly TK010



Thoracic Metzenbaum Scissors TMS10



Thoracic Right Angle TRK10

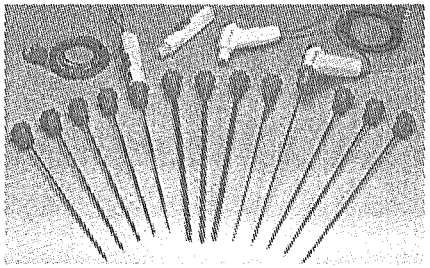
Price effective 11/12/95

Item	Code	Description	Sales unit	Price for 1–2 sales units	Price for 3–5 sales units	Price for 6–11 sales units	Price for 12+ sales units

10 MM DISPOSABLE HANDHELD INSTRUMENTS CONT

08689	ENDLC	Lung Forceps With Ratchet	EACH	233.00	224.00	203.00	176.00
84090	MBA10	Modified Allis Clamp	EACH	233.00	224.00	203.00	176.00
08692	TDC10	Debakey With Ratchet	EACH	233.00	224.00	203.00	176.00
08691	TGC10	Glassman Clamp With Ratchet	EACH	233.00	224.00	203.00	176.00
75798	TMS10	Thoracic Metzenbaum Scissors	EACH	255.00	244.00	224.00	216.00
08693	TRK10	Right Angle Kelly With Ratchet	EACH	233.00	224.00	203.00	176.00

*TRADEMARK



Electrosurgery Probe Plus II

ELECTROSURGERY - CAUTERY, SUCTION AND IRRIGATION - DISPOSABLE

PROBE PLUS II

89012	EPH01	Pistol Grip Handle, Foot Control Electrosurgery	EACH	126.00	123.00	122.00	120.00
89013	EPH02	Pistol Grip Handle, Hand Control Electrosurgery	EACH	126.00	123.00	122.00	120.00
89014	EPH03	Pencil Grip Handle, Foot Control Electrosurgery	EACH	126.00	123.00	122.00	120.00
89015	EPH04	Pencil Grip Handle, Hand Control Electrosurgery	EACH	126.00	123.00	122.00	120.00
89016	EPS01	Hook Electrode, 5 mm shaft, 34 cm length	EACH	77.00	74.00	73.00	71.00
89017	EPS02	Spatula Electrode, 5 mm shaft, 34 cm length	EACH	77.00	74.00	73.00	71.00
89018	EPS03	Right Angle Electrode, 5 mm shaft, 34 cm length	EACH	77.00	74.00	73.00	71.00
89019	EPS04	Curved Dissector Electrode, 5 mm shaft, 34 cm length	EACH	77.00	74.00	73.00	71.00
89020	EPS05	Hook Electrode, 5 mm shaft, 29 cm length	EACH	77.00	74.00	73.00	71.00
89021	EPS06	Spatula Electrode, 5 mm shaft, 29 cm length	EACH	77.00	74.00	73.00	71.00
89022	EPS07	Right Angle Electrode, 5 mm shaft, 29 cm length	EACH	77.00	74.00	73.00	71.00
89023	EPS08	Curved Dissector Electrode, 5 mm shaft, 29 cm length	EACH	77.00	74.00	73.00	71.00
89024	EPS09	Needle Electrode, 5 mm shaft, 29 cm length	EACH	77.00	74.00	73.00	71.00
89025	EPS10	Pool/Sump Suction and Irrigation, 10 mm shaft, 34 cm length	EACH	77.00	74.00	73.00	71.00
89026	EPS11	Suction and Irrigation, 10 mm shaft, 34 cm length	EACH	77.00	74.00	73.00	71.00
89027	EPS12	Stone Retrieval, 10 mm shaft, 34 cm length	EACH	77.00	74.00	73.00	71.00
89028	EPS13	Accessory Port, 5 mm shaft, 29 cm length	EACH	77.00	74.00	73.00	71.00

CORDS

84025	EAC01	Active Cord - Bovie Pin to 90 deg Jack	EACH	113.00			
84026	EAC02	Active Cord - Banana Plug to 90 deg Jack	EACH	113.00			
84805	EAC03	Bovie Pin	EACH	30.00			

ADAPTOR

84019	A2000	ESU Adaptor - Bovie Pin to Banana Plug	EACH	45.00			

Price effective 11/12/95

*TRADEMARK

Johnson & Johnson MEDICAL PTY. LTD. A.C.N. 000 160 403

Item	Code	Description	Sales unit	Price for 1–2 sales units	Price for 3–5 sales units	Price for 6–11 sales units	Price for 12+ sales units

ENDOPATH* BIPOLAR FORCEPS

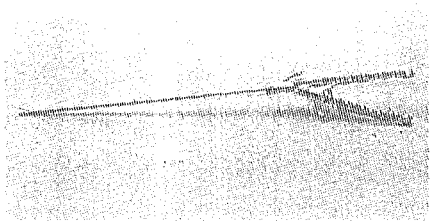
55524	EBF01	5 mm Rotating Shaft, 33 cm Long with Macro Jaw	EACH	173.00	157.00	150.00	142.00
55525	EBF02	5 mm Rotating Shaft, 33 cm Long with Micro Jaw	EACH	173.00	157.00	150.00	142.00

CORDS

55526	EBC01	Active Cord - Two Banana Pin Connectors	EACH	113.00			
55527	EBC02	Active Cord - Single Coaxil Pin Connector	EACH	113.00			

5 MM LAPAROSCOPIC NEEDLE HOLDER

81964	E0705R	Needle Holder	EACH	2974.00			

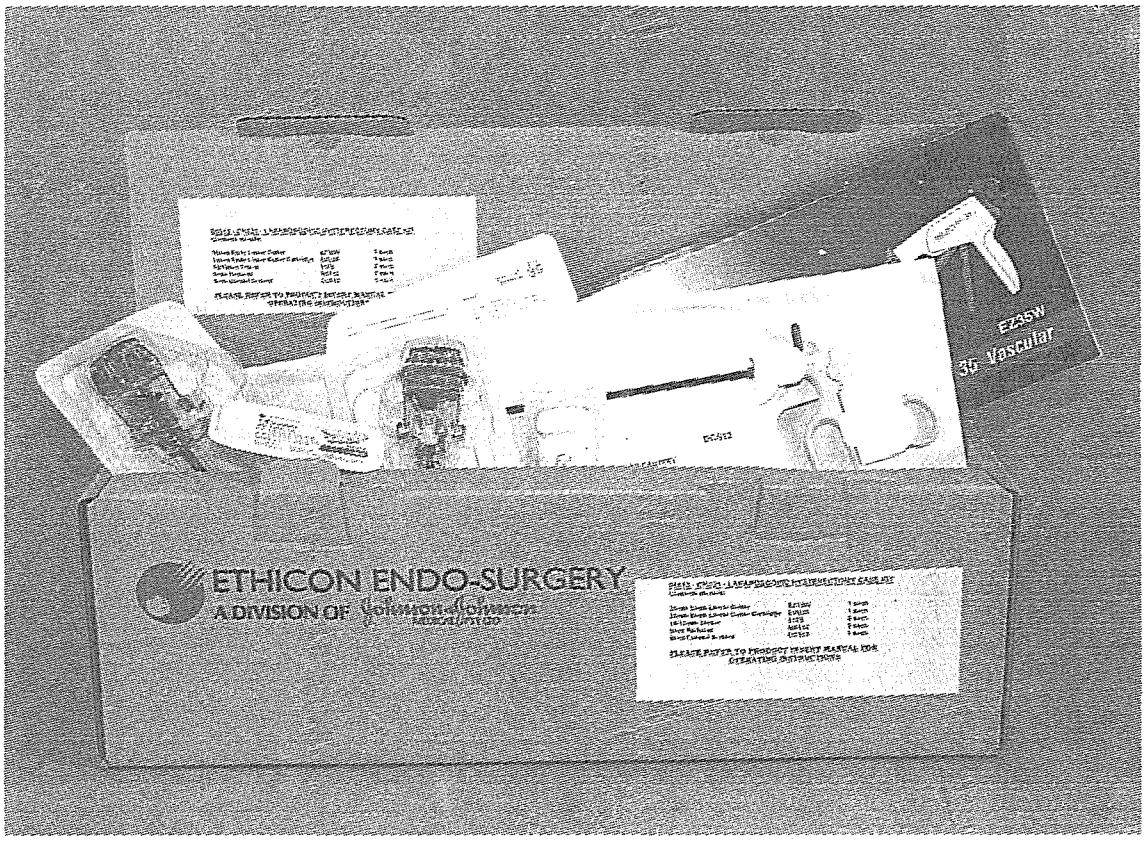


Needleholder E0705R

Price effective 11/12/95

*TRADEMARK

CUSTOMISED CASE KITS



ıse Kits allow you to choose and package instruments that suit your surgical needs.

- Customised and convenient for your staff and surgeons
- Cost effective for O.R. and Supply Management
- Environmentally responsive materials and packaging

Speak to your local Product Specialist for details.

ts the stringent requirements of Johnson & Johnson's Worldwide Environmental Policy

Appendix 3 Operators Manual For Cook Morcellator

COOK® TISSUE MORCELLATOR™

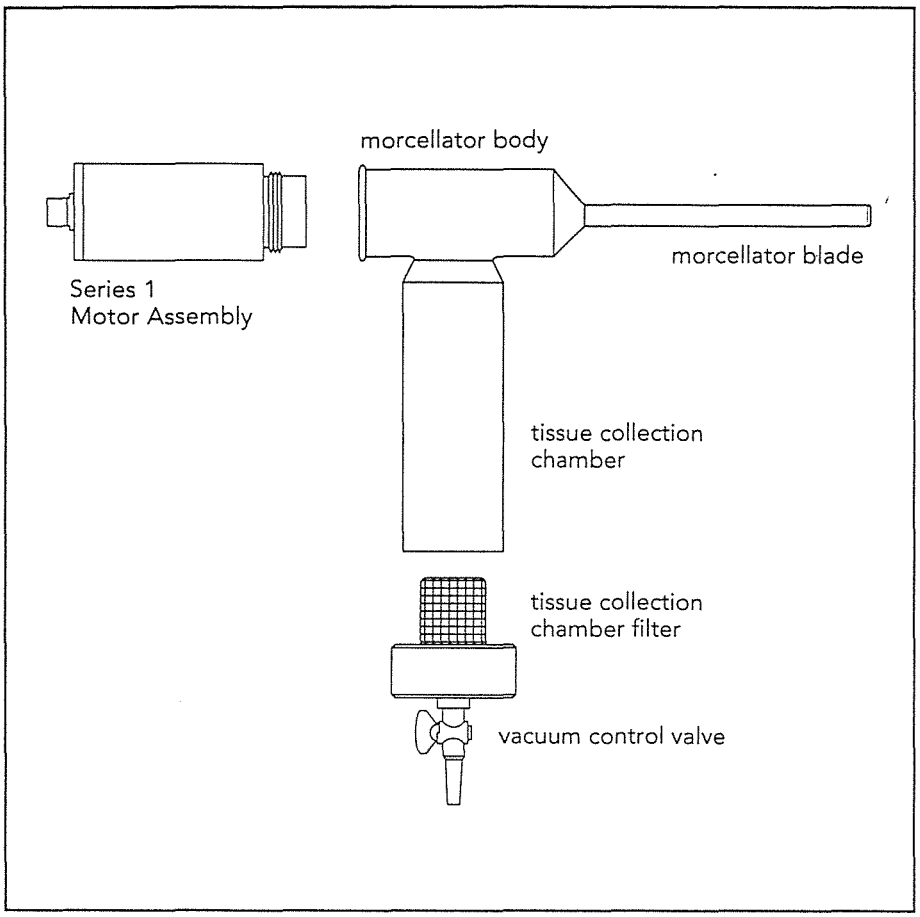
Operators Manual

COOK UROLOGICAL INCORPORATED
A COOK GROUP COMPANY
1100 West Morgan Street P.O. Box 227
Spencer, Indiana 47460 U.S.A.
Phone: 812 829-4891
Telefax: 812 829 2022
Toll Free: 800 457-4448

COOK OB/GYN®
A DIVISION OF COOK UROLOGICAL INC.
1100 West Morgan Street P.O. Box 271
Spencer, Indiana 47460 U.S.A.
Phone: 812 829-6500
Telefax: 812 829 2022
Toll Free: 800 541-5591

MRCL692

CAUTION: The Cook® Tissue Morcellator™ is intended for use by physicians trained and experienced in techniques for tissue morcellation.



The Cook® Tissue Morcellator™ rotary scalpel is used for morcellation and removal of dissected tissue under direct vision, open surgical procedures, and/or endoscopic procedures when used in conjunction with the LapSac™.

Operator Instructions:

DANGER: Risk of explosion. Do not operate the morcellator in the presence of flammable anesthesia and other volatile materials.

CAUTION: Electrical shock hazard. Do not attempt to remove the cover from the power supply assembly, or disassemble the morcellator motor.

If the power supply or motor fail to perform properly, contact Customer Service (800 457-4448 or 800 541-5591) for a return authorization.

In the event that you must return the power supply assembly for service, it should be cleaned and packed in the original case for shipping.

Assembly:

1. In the sterile field, remove the morcellator body assembly from the sterile packaging.

2. In the sterile field, attach the non-sterile motor assembly to the morcellator body, taking care to avoid entangling the sterility sleeve in the motor threads.

3. Attach the non-sterile motor cord to the motor assembly. **CAUTION: The Series 1 Motor Assembly is intended for use with a Cook® Series 1 Power Supply only. Do not attempt to substitute other power supplies.**

4. Pull the sterility sleeve over the motor and cord.

5. Maintaining the sterile field, attach vacuum tubing to the vacuum control valve on the morcellator. Connect vacuum tubing to wall suction (20 to 28 in. Hg).

6. Plug the power cord to a hospital grade receptacle and position the foot pedal switch appropriately.

7. The device is now ready for use.

Operation:

Place morcellator blade directly upon tissue to be morcellated.

Open the vacuum control valve on the morcellator body.

CAUTION: Direct application of vacuum to an insufflated peritoneum will result in loss of insufflation medium. Morcellator must be used in conjunction with a LapSac™ during endoscopic procedures. Not recommended for use with other tissue isolation products.

Depress foot pedal to activate morcellator blade. The foot pedal is a threshold switch; morcellator blade speed is constant. To stop blade, release foot pedal switch. **NOTE: The vacuum control valve and foot pedal can be turned on and off at the physician's discretion throughout the procedure.**

Advance morcellator cannula directly into tissue to be morcellated. To achieve optimal morcellation use measured, methodical strokes in favor of forcibly driving the sheathed rotary bevel into tissue. Continue until desired morcellation is complete.

WARNING: The LapSac™ can be cut if manual tension is not maintained. The assisting surgeon must maintain manual tension to prevent folds of the LapSac™ from being drawn into the morcellator. The LapSac™ should be monitored by video throughout the morcellation.

5. To remove tissue from collection chamber:

a. Close vacuum control valve.

b. Remove base from the tissue collection chamber.

Disassembly:

1. Turn off wall suction.

2. Unplug power cord from wall outlet.

3. Remove the sterility sleeve and disconnect the motor cable from the morcellator motor.

4. Disconnect the vacuum tube from the vacuum control valve.

5. Remove the motor from the morcellator body.

6. Dispose of the morcellator body properly.

Morcellator Motor and Power Supply Assembly Cleaning Instructions:

CAUTION: Do not attempt to sterilize the motor or power supply assembly by steam autoclave, ethylene oxide gas (ETO), or immersion in disinfectant solution.

1. Clean the outside surfaces with a disinfectant solution.

2. Wipe the outside surfaces with a damp cloth and allow to dry before storing or reusing.

Cook® Tissue Morcellator™ Body Assembly

Cook Urological®
Order Number: 410010

Cook Ob/Gyn®
Order Number: KCTM-410010

The Cook® Tissue Morcellator™ Body Assembly is supplied sterile in peel-open packages and is intended for one-time use.

Description:
Polyvinylchloride morcellator and tissue collection chamber with vacuum control valve and stainless steel cutting cannula assembly

Stainless steel collection chamber filter

Polyurethane sterility sleeve 200 cm long

Cook® Series 1 Tissue Morcellator™ Power Supply Assembly

Cook Urological®
Order Number: 410000

Cook Ob/Gyn®
Order Number: KCTM-410000

Components: (Supplied non-sterile)

Cook® Series 1 Power Supply
Line voltage: 120 V AC
Line Frequency: 60 Hz
Line Current: 1.4 A maximum

Power cord

Foot switch

Motor cable with waterproof connector

Cook® Series 1 Tissue Morcellator™ Motor Assembly

Contraindications:

The Cook® Tissue Morcellator™ is contraindicated for the morcellation of bone and for use in liposuction procedures.

Precautions and Warnings:

The Cook® Tissue Morcellator™ should be used during laparoscopic, pelviscopic and percutaneous procedures only by physicians with adequate training in these procedures.

A comprehensive preoperative medical history and physical examination are suggested. Radiographic evaluation and laboratory tests may be included.

The Cook® Tissue Morcellator™ will cut and aspirate tissue when vacuum is applied in combination with blade rotation and direct contact with tissue. **WARNING: Do not place the blade in contact with tissue which is not intended to be morcellated.**

Direct contact of the rotating cutting edge of the blade with metal (e.g.: cannula, endoscope, or other instruments) can cause damage to the morcellator blade. If such contact should occur, the entire morcellator body assembly should be discarded and a new unit substituted. Replacement blades are not available for the morcellator.

Patent Pending

Appendix 4 Preoperative Instructions for Patients

(Hulka, 1985)

12.3 INSTRUCTIONS FOR OUTPATIENT SURGERY

Pre-operative Instructions

A. When you come the morning of surgery, come directly to the Day-Op Room.

Directions: Take the elevators to the 2nd floor and follow the signs marked Out-Patient Surgery. *Do not check in or go anywhere else first.*

The Night Before Surgery

1. Eat a supper that will not upset your stomach.
2. Do not eat or drink anything after midnight. Nothing in the morning—no coffee, juice or water, not even a stick of gum! It is extremely dangerous to be put to sleep or sedated when you have food or liquid in your stomach.
3. Remove all fingernail polish and toenail polish.
4. Take a complete bath (shower or tub) and shampoo your hair.
5. Do not drink any alcoholic beverages for 24 hours before or after your operation. Alcohol may increase the depth of your anesthesia or the effect of the medicines you are given.

The Day of Your Operation

1. Do not apply any make-up, no eye make-up, face make-up or lipstick.
2. If you have long hair, braid it or secure it with a rubber band.
3. All hairpins, hair clasps or combs must be removed.
4. All dentures or bridges, contact lens and glasses must be removed before going to the Operating Room.
5. Please do not wear any jewelry, earrings, rings, watches, medals, etc.
6. Wear any kind of comfortable clothing, especially low heeled shoes.

B. In any event that your physical condition changes (for example, if you develop a cold, persistent cough, fever, flu, or an important change in the condition for which you are having the operation) please notify Dr _____, the resident on call, by calling the Main Hospital number, _____, and asking for him or her.

C. If you have any questions or need to cancel your surgery, feel free to call us in the Day-Op Room on Monday through Friday from 7:30 a.m. to 3:30 p.m. Phone: _____ or _____.

Responsible Adult

D. A responsible adult, who drives, MUST accompany you in a car to the hospital and come up to the Day-Op Room with you. Due to our limited amount of space we must ask that no more than (2) two people come with you. The drugs and/or anesthesia which you receive will make it unsafe for you to drive a car for 24 hours, walk back to your home, or go home alone by public conveyence. The responsible adult may be a parent, friend, husband or wife. If a responsible adult and transportation is not with you when you arrive in Day-Op your operation *WILL NOT* be performed.

Appendix 5 Postoperative Instructions for Patients

(Hulka 1985)

12.4 POSTOPERATIVE INSTRUCTIONS

Day Op Post-Op Orders

The anesthetic or drugs given you today for your operation will remain in your body for some time. You may feel dizzy or lose your sense of balance, your fine muscle control will be changed, and your judgment will be different. Your reaction time, such as in driving a car, will be slowed. *And you may not be able to tell any of these.*

So we have some strict instructions:

THE FIVE D'S

1. DO NOT *DRIVE* (or use anything more complicated than a radio, television, or refrigerator.)
2. WATCH OUT FOR *DIZZINESS*—move slowly, take your time. Sudden position changes can even cause nausea.
3. DO NOT MAKE ANY IMPORTANT *DECISIONS*—you may change your mind tomorrow.
4. DO NOT *DRINK* ALCOHOLIC BEVERAGES—the drugs may cause your reaction to alcohol to be dangerous.
5. *DISCUSS* ANY QUESTIONS YOU MAY HAVE WITH YOUR DOCTOR—
   _____, M.D., telephone number _____. Our Day Op number is _____.

About eating: don't, if there is any question of whether you feel nauseated or sick at your stomach. It is probably best to stay on clear liquids and soft foods today.

Be sure and ask your doctor about taking or continuing any medications.

In general, you should be completely recovered from your anesthetic by tomorrow.

TO PATIENTS WHO HAVE JUST HAD LAPAROSCOPIC STERILIZATION

Your operation is over. The following are answers to typical questions asked after surgery:

What Types of Side Effects May Occur?

1. There may be an unpredictable amount of reaction to the anesthesia. The reaction can range from practically *no symptoms* to possibly three or four days of *feeling tired* while recuperating from the medication and excitement.
2. You may have a *sore throat* for the first twenty-four hours. The sore throat may be due to an airway placed in your throat if you were put to sleep.
3. *Shoulder pain* or *chest pain* may occur for a day or two. This pain is due to gas remaining in your abdomen. The gas irritates your abdominal wall and is felt in your chest and shoulder. If you are particularly uncomfortable you can be relieved by lying flat and applying a heating pad to your shoulder.
4. You may note *vaginal spotting* for a day or two. This is not your period but is the result of an instrument used to move your uterus during surgery.
5. There may also be some *soreness in your arm at the IV needle site*. Wet warm soaks will help.
6. You may notice some *bruising across your abdomen*. This is a result of the doctor lifting the fatty tissue during surgery and will go away as any other bruise would.
7. If you had clip or band sterilization you may have *menstrual cramp type pain* for a day or two. This results from a nerve being pinched and is not dangerous.

How Should I Care for the Incision?

The bandaids which are placed on the skin opening should be left in place for three to four days. Replace the bandaid if it should get wet when showering. Swimming or tub baths are allowed in five to six days. After three to four days, the incision can be treated as any other cut on the skin.

Do the Stitches Need to Be Removed?

No. There are no stitches in the skin. Should some of the buried stitches in the incision fester or come through to the skin, it is advisable to have them removed by one of our doctors or by your local doctor.

When Can I Resume Usual Activities?

Full physical activity is allowed as soon as you feel up to it. It is advisable to rest and let

another adult take on responsibilities the day and evening of your surgery. Some women return to work the day after surgery, others in two to three days—each person may vary. Intercourse may be resumed as soon as you feel comfortable.

What Should I Do in Case a Problem Arises?

In case problems should arise, it is advised that a responsible adult remain with you the evening of your surgery. Call the hospital operator (_____) and ask for the Gynecology Resident on call OR come to the Emergency Room if any of the following should arise:

1. Fever greater than 100 degrees.
2. Increasing abdominal swelling (it is normal to feel some bloating)
3. Intense or progressively worsening abdominal pain
4. Bleeding from the incision that cannot be controlled by a bandaid or a light dressing.

Do I Need Protection Against Pregnancy?

If you are mid-cycle and have *not* been on oral contraceptive (the Pill), there is a rare chance you could get pregnant during this cycle. Use foam *and* condoms or diaphragm until your next period. After your period no further method of contraception is needed.

Are There Any Emotional Changes after Surgery?

Your feelings may vary after your surgery. Some women report feelings of sadness, others feelings of relief. Either reaction is normal and emotionally you will begin to "level off" as you resume your daily life pattern.

Do I Have to Return to the Hospital to be Checked after Surgery?

No. However, if you have questions or if you feel that you need to see a physician, call _____ and make an appointment in the Gyn Outpatient Surgery Follow-up Clinic.